No. 24-1365

In the United States Court of Appeals for the District of Columbia Circuit

DOCTORS FOR DRUG POLICY REFORM; BRYON ADINOFF, DR.,

Petitioners

v.

DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondents

On Petition for Review of Orders of the Drug Enforcement Administration (Oct. 28, 2024 and Nov. 25, 2024)

PETITIONERS' APPENDIX
VOLUME 3 OF 6
App.691 to App.958

Austin T. Brumbaugh
D.C. Circuit Bar No. 65727
YETTER COLEMAN LLP
811 Main Street, Suite 4100
Houston, Texas 77002
713-457-3099

Counsel for Petitioners

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Dated: February 17, 2025

Respectfully submitted,

/s/Austin T. Brumbaugh

Austin T. Brumbaugh
D.C. Circuit Bar No. 65727
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811 Main Street, Suite 4100
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713-457-3099

Attorney for Petitioners

Bryn Spejcher
Docket No. DEA–1362

TO: Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

FROM: Bryn P. Spejcher
217 Edgebrook Drive
Bloomingdale, IL 60108

Date: September 18, 2024

RE: Docket No. DEA – 1362

Dear DEA Administrator,

Thank you for your email regarding my request for a hearing on the proposed rule to transfer marijuana from Schedule I to Schedule III of the Controlled Substances Act. I appreciate the opportunity to provide additional information.

My name is Dr. Bryn Spejcher (female) and I am an "interested person" as defined in the DEA's regulations, as I have been directly and adversely affected by the effects of marijuana. Specifically, I experienced Cannabis-Induced Psychosis on May 28, 2018, which significantly impacted my consciousness and led to severe legal and personal consequences. This experience has given me a firsthand understanding of the potential dangers and risks associated with marijuana use, especially in its current unregulated form under Schedule I.

The evidence I intend to present at the hearing will include personal testimony and supporting documents outlining my case of Cannabis-Induced Psychosis, as well as expert opinions on the potential risks of rescheduling marijuana without appropriate safeguards. I believe that this testimony is crucial in highlighting the mental health dangers that marijuana can pose, which need to be carefully considered before any changes to its legal classifications are made.

Attachments included:

- Bryn Spejcher's Testimony
- Dr. Kris Mohandie – CA Licensed Psychologist (portions of the full report; information details hidden to protect the privacy of parties involved and court case is ongoing/appeal)
- Robert Schwartz – CA Criminal Defense Attorney (letter)
- Dr. Daniel Buffington – Clinical Pharmacologist and Toxicologist (letter)
- Ventura County, CA - criminal court docket of sentencing - 1/23/2024 and 3/13/2024

Please let me know if any further information is required. I would appreciate confirmation of receipt of this response and look forward to hearing from you regarding the next steps in this process. Thank you for your time and consideration.

Sincerely,

Bryn Spejcher, Au.D., CCC-A, F-AAA

Bryn Spejcher, Au.D.

Date

9-18-2024

Bryn Spejcher's Testimonial
Docket No. DEA–1362

TO: Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

FROM: Bryn P. Spejcher
217 Edgebrook Drive
Bloomingdale, IL 60108

Date: September 18, 2024

RE: Docket No. DEA – 1362

Please consider this testimonial which provides details surrounding my background and the horrific criminal case that transpired in Ventura County, California, involving cannabis use.

Growing up in suburban, Illinois, I experienced a childhood filled with love and stability in a Christian household alongside my parents, brothers and many pets. I engaged in various activities such as sports, music and academics. Adding a challenge, I was diagnosed with bilateral severe, sensorineural hearing loss by the age of 3, and have utilized binaural hearing aids since the age of 4 (30-year use). Throughout my life, I never engaged in drugs nor have I partaken in them illegally, never committed violence nor have a history of mental illness.

Following academic pursuits, culminating in a doctorate in Audiology from Washington University in St. Louis, School of Medicine, I embarked on a career path aimed at helping others with hearing impairments. In 2017, I began working as a Senior Audiologist in Thousand Oaks, California area with UCLA Health, eager to make a difference in the lives of patients.

The tragic event occurred on May 28, 2018, resulting in the death of my friend and permanent self-inflicting wounds, due to a severe cannabis-induced psychosis that I experienced after consuming, unknowingly, a potent dose of legal marijuana. At first, it was unknown what happened, so I was charged with first degree murder and ordered to restrict from practicing Audiology. This event plunged me into a period of profound grief, depression, fear and introspection as I waited for what was to come next.

After a week of incarceration, I was released on bail, then I received years of medical and mental health treatment, while being involved in a serious legal criminal case. It wasn't until 3 years post-incident, that it was brought to my attention that this event occurred because of a possible drug-induced psychosis, and I only had THC in my toxicology report. As the years passed in preparation for trial, I have been interviewed by multiple forensic psychologists who administered several evaluations. All specialists agreed this event was a **cannabis-induced psychosis**, and that I had no prior or post mental health issues. This determination influenced the district attorney's office (People of California) to significantly reduce my criminal charge to involuntary manslaughter on September 27, 2023.

The subsequent legal proceedings led to my conviction of involuntary manslaughter, accompanied by three years' probation, restitution, a mandate of 52 domestic violence classes, and to contribute 100 hours of community service to raise awareness and educate about the potential dangers of marijuana.

A generalized and condensed story the night of this tragic event:

Without my knowledge or consent, the decedent prepared a very intense, unusual dose (unbeknownst as "stacking" or "layering") of his supply of legal, high-potency THC marijuana, and pressured me, a novice and infrequent user, to inhale out of his bong. This caused in me an unforeseen, induced psychosis and potential self-defense that harmed the decedent and myself. The criminal court Judge agreed that this was an unforeseeable event, extremely unusual and ordered a lenient outcome.

The years since that life altering night, has been one of immense pain and regret. Like many others, I was unaware of the potential risks associated with high-potency THC. I am no one special. This can happen to anyone. I've promised to the court that I will never touch any cannabis substance again, and to spread awareness and education on cannabis-induced psychosis.

The normalization of potent strains of marijuana has perpetuated the misconception that cannabis is inherently harmless. However, this story serves as a stark reminder of the dangers lurking within. The technique of "milking" or "layering" or "stacking" a bong, which I unknowingly was pressured and tricked into, can significantly amplify the effects of THC, leading to catastrophic psychological reactions in naïve, susceptible individuals. I wish this on no one.

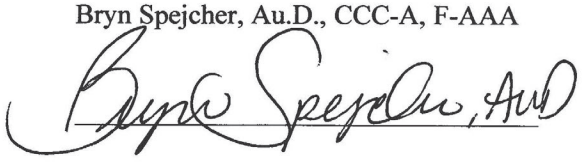
My hope is that sharing my testimony can prevent others from experiencing similar tragedies. If I had known more about the potential dangerous and deadly effects of high-potency marijuana, this tragedy would not have occurred. I am deeply concerned about the cases of other people who have lost their lives or have been severely impacted, and having no idea that cannabis could have played a role. It's a sobering reminder of the urgent need for awareness and education surrounding the risks associated with high-potency THC.

I believe I would be of "interested persons" as part of your hearing, as my testimonial is true and factual, proven by many professionals involved within this tragic criminal case.

Thank you for taking the time to read my testimonial.

Sincerely,

Bryn Spejcher, Au.D., CCC-A, F-AAA



Date

9-18-2024

Docket No. DEA-1362

KRIS MOHANDIE, PH.D., ABPP
LICENSED PSYCHOLOGIST
LICENSE# PSY12105
P.O. BOX 88
PASADENA, CALIFORNIA 91102-0088
(626) 627-8388

March 3, 2023

Audrey Nafziger
Senior Deputy District Attorney
Ventura County DA's Office Homicide Unit

Re: People v. Bryn Spejcher

Dear Ms. Nafziger:

Pursuant to your Court Order, this is a psychological report of my findings and opinions in the matter of **People v. Bryn Spejcher.** Ms. Spejcher has pled not guilty to the following charge and special allegation: 187 (a) murder and a special allegation of personally used a deadly and dangerous weapon(s), to wit. a knife, said use not being an element of the above offense, within the meaning Penal Code Section I2022(b)(I) and causing the above offense to be a serious felony within the meaning of Penal Code section I192.7(c)(23).

It is noted that any information not available at the time of this report might alter the opinions included herein. A copy of my resume is attached.

DATABASE

Court Documents

- Ventura County Criminal Complaint, dated 6/4/18
- Preliminary Hearing Transcript, dated 5/7/19

Police Reports

- VCSO Initial Crime Report, by Czyrklis, dated 5/28/18
- Inner Scene Crime Log
- Emails from [redacted]
- Ventura County Sheriff's Office, Detective Narrative, dated 6/1/18
- Ventura CLETS Bryn Spejcher
- DA Evidence View Report, dated 5/31/22
- Sgt. King Supplemental Report re. Dog Park incident, dated 5/25/19
- Sgt. King Supplemental Report re. Dog Park incident, dated 5/16/18
- Call for Service, dated 5/28/18
- Ventura County Jail Booking Paperwork, dated 5/31/18
- Ventura County Spejcher Social Media Summary Supplemental, dated 7/23/18
- Ventura County Spejcher Medical Records and Injuries, dated 6/19/18

- Ventura County Supplemental Report [redacted] by Rodriguez, dated 5/31/18
- Ventura County Supplemental Report re. Smoking Bong, dated 7/25/18
- Ventura County Supplemental Report Found Bong, by Steve Jenkins, dated 7/26/18
- Ventura County Sheriff's Report Suspect Miranda Interview, dated 6/4/18
- Narcotics Investigation Reports
    - Ventura County Sheriff's Report, dated 7/31/18
- Ventura County Sheriff's Supplemental Report with Supplemental Interviews with Bryn by Jenkins, dated 6/15/18
    - 5/29/18 interview
    - 5/30/18 interview with her brothers in the room
- Ventura County Sheriff's Supplemental Interview with [redacted], dated 6/18/18 (Interview 6/13/18)
- Ventura County Sheriff's Supplemental Interview of [redacted] dated 6/14/18 (interview 6/3/18)
- Multiple Miscellaneous Ventura County Supplemental Reports

Audio/Video

- [redacted] 911 Call, dated 05/28/18
- Audio Recordings of:
    - AMR Brill
    - [redacted]
    - [redacted]
    - VCFD Martin-Francis Interview
    - 1st ICU Interview of Bryn Spejcher, dated 5/28/18 @ 2234
    - 2nd ICU Interview of Bryn Spejcher, dated 5/29/18 @ 1100
    - Miranda Interview of Bryn Spejcher, dated 5/31/18 @ 1900
    - [redacted] dated 6/6/18
    - [redacted], dated 6/6/18
    - [redacted], dated 6/13/18
    - [redacted] 1 & 2
    - [redacted]
    - [redacted] dated 6/12/18
    - Contact with Bryn, dated 5/30/18 @ 1655
    - [redacted] dated 6/12/18
    - [redacted], dated 6/12/18
    - EMT Brandon Gillette
    - Evidence Collection from roommate [redacted]
    - Fire Captain P. Corsi Statement
    - [redacted]
    - [redacted], dated 5/29/18
    - [redacted] at Hospital, dated 5/30/18
    - [redacted] Evidence Collection
    - [redacted] Interview
    - Next of Kin Notification
    - Phone Call to [redacted] about smoking bong
    - [redacted] Interview, dated 6/12/18

  - [redacted] dated 6/12/18
  - [redacted], dated 6/13/18
  - VCFD Kevin Lungren
  - VCFD Spencer Burris
  - [redacted] Follow-up Interview 2
  - [redacted] Interview 1
  - Walk thru with [redacted] 1&2, dated 6/4/18
  - [redacted]
  - Death Notification to [redacted] 1& 2
  - [redacted]
- Body Cam Footage (multiple), dated 5/28/18
  - Bryn Spejcher
  - Body Cam Interview Bry Spejcher by Officer Czyrklis in Hospital, dated 5/28/18 @ 0235, part 1 and 2
  - Body Camera of Walk Thru with [redacted]

Transcripts

- [redacted] 911 Call, dated 5/28/18
- BWC Recording of Bryn Spejcher during Initial Contact by Ventura County Sheriff's Sergeant Russell King, labeled 5/31/18 (NOTE: wrong date, must be 5/28/18)
- BWC Recording of Bryn Spejcher during Initial Contact by Ventura County Sheriff's Sergeant Scott Norris, labeled 5/31/18 (NOTE: wrong date, must be 5/28/18)
- Audio Recorded First Hospital Interview of Bryn Spejcher by Ventura County Sheriff's Captain Steven Jenkins, dated 5/28/18
- Audio Recorded Second Hospital Interview of Bryn Spejcher by Ventura County Sheriff's Captain Steven Jenkins, dated 5/28/18 (per testimony its 5/29/18)
- Audio Recorded Miranda Interview of Bryn Spejcher by Ventura County Sheriff Captain Steven Jenkins, dated 5/31/18

Photographs

- Crime Scene Photos
- Photos from [redacted]
- Text Message with [redacted]
- [redacted] Sketch Drawing
- Suspect and Clothing
- Crime Scene Initial
- Vehicles
- Suspect Injuries
- Miscellaneous Crime Scene
- Crime Scene and Hospital
- Suspect in Hospital
- Autopsy Photos
- Spejcher's Room
- Suspect and Dog
- Initial Note to ICU Nurse, undated (but 5/28/18)
- Misc Notes to ICU Nurses
- 5/28/18 Note
- Notes Written During 5/28/18 interview
- Picture from [redacted] (ex-boyfriend)-text exchange with [redacted]
- Photo Release
    - Photos of Ms. Spejcher at hospital
    - Photos of victim at Medical Examiner
- [redacted] letter to the Judge, dated 7/12/18
- Victim in Life Photos
- Hospital handwritten notes by Bryn Spejcher
- Evidence Photos

Other Reports

- VCSD Autopsy Materials (including photos), dated 5/31/18
- Autopsy Report, dated 5/29/18
- Miscellaneous VC Medical Examiner Reports
- NMS Toxicology Supplemental Report re. Chad Omelia, dated 6/10/18
- NMS Toxicology Supplemental Report re. Chad Omelia, dated 7/24/18
- NMS Report, dated 7/2/18
- Outer Crime Scene Log
- Crime Scene Documentation
- NMS Supplemental Report, dated 7/3/18
- Communications Log, dated 3/20/19
- Miscellaneous Controlled Substance and Chain of Custody Reports
- Controlled Substance Section Discovery Packet
- Crime Scene Investigation Report, dated 8/22/18
- Crime Scene Investigation Report, dated 5/30/18 (photo documentation)
- DNA Related Reports
- Miscellaneous VCSO Forensic Sciences Lab Reports
- VCSO Toxicology, dated 6/1/18

- Toxicology Section Discovery Packet
- Toxicology Supplemental Report, dated 7/5/18
- NMS Toxicology Report, dated 3/1/20
- NMS Test 27100 Controlled Substance Panel List

Other Materials
- Bryn Spejcher Phone Download
- Bryn Spejcher Snapchat Return
- Chad Omelia Phone Download
- [redacted] v. Spejcher small claims action (related to biohazard cleanup), dated 4/29/19
- [redacted] Interview, dated 11/22/19
- TRO Application by Bryn Spejcher against [redacted] dated 11/5/19

Mental Health Records
- [redacted] Treatment Records
- [redacted] LMFT, MS records

Medical Records
- Los Robles Hospital (including):
  - Discharge summary, dated 6/1/18
  - Emergency Provider Report, dated 5/28/18 @ 150
  - Psychiatric Consultation Note, dated 6/1/18
  - Psychiatric Consultation Note, dated 5/31/18
  - Toxicology Screen, dated 5/28/18
  - Toxicology Screen, dated 5/29/18
  - Quest Diagnostics Drug Screen, dated 5/30/18
  - Toxicology Screening Comparisons

Other Materials
- Medical Records for Ms. Spejcher's dog Arya

Other Expert Reports
- Letter from Timothy Fong, dated 12/2/21
- Spejcher Affidavit of William Wirshing, MD dated 6/24/21

Interview of Bryn Spejcher, dated 1/23/23

Psychological Testing
- Structured Interview of Reported Symptoms, dated 1/23/23
- Minnesota Multiphasic Personality Inventory-2 (MMPI-2), dated 1/23/23

References

American Psychiatric Association. (2022). *Diagnostic and statistical manual of mental disorders, fifth edition, text revision (DSM-5-TR).* American Psychiatric Association: Washington, DC.

CASE ANALYSIS

On May 28, 2018, Ms. Spejcher, who had no history of violence, suicidal behavior or psychotic thinking prior to or after the incidents (meaning hours later), consumed marijuana and became acutely psychotic and stabbed the victim multiple times killing him, then stabbed herself repeatedly.

a. *She had no history of violence, suicidal behavior, or psychotic thinking prior to the incident.*

1)

Expanded details confidential to the court case

2)

b. *Leading up to consuming the marijuana with the victim, she had had a normal day, and there was no evidence whatsoever of any psychotic symptoms. Ms. Spejcher was in a*

normal state of mind prior to the violent events of that evening, prior to her using the cannabis.

1)

Expanded details confidential to the court case

2)

3)

c. *Ms. Spejcher was an inexperienced or naïve user of marijuana but never experienced any of these symptoms prior to this evening. There was no evidence of any other drugs or intoxicants in her system, and the victim-who likely consumed the same "bong hit"-similarly tested positive exclusively for cannabis.*

1)

Expanded details confidential to the court case

2)

e. *She appeared impervious to pain on the BWC, not only to her self-inflicted stabbing but also the uses of force by first responders. This is often seen in acutely psychotic individuals.*

1)

Expanded details confidential to the court case

2)

3)

f. *She reported hearing voices, seeing visions, and having prominent delusions that directly related to her violent assault upon the victim, as well as her own self-injurious behavior. Her reality testing was severely impaired and she grossly misperceived reality.*

1)

Expanded details confidential to the court case

police interviews. The description by Mr. Oliveira as her appearing "possessed" is consistent with acute psychosis.

1)

2)

Expanded details confidential to the court case

h. Ms. Spejcher's attack and self-inflicted injuries were highly resolved and evidenced a continuity of purpose consistent with her delusions and command hallucinations.

1)

2)

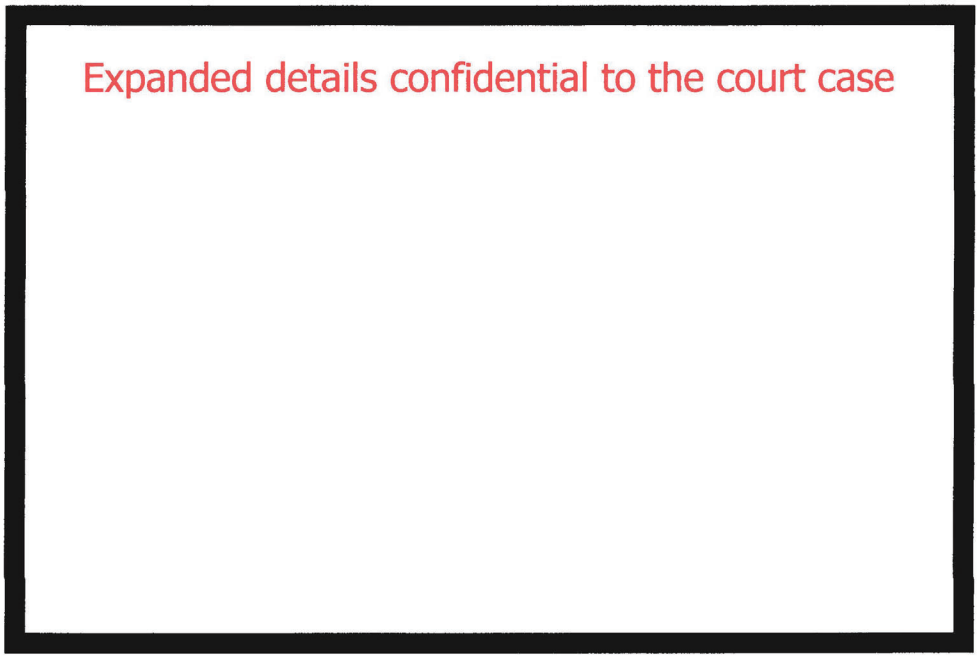
Expanded details confidential to the court case

i. Ms. Spejcher's psychotic state resolved within hours and it appears it took her some time to become consistently oriented and comprehend what happened and what reality was within this window.

1)

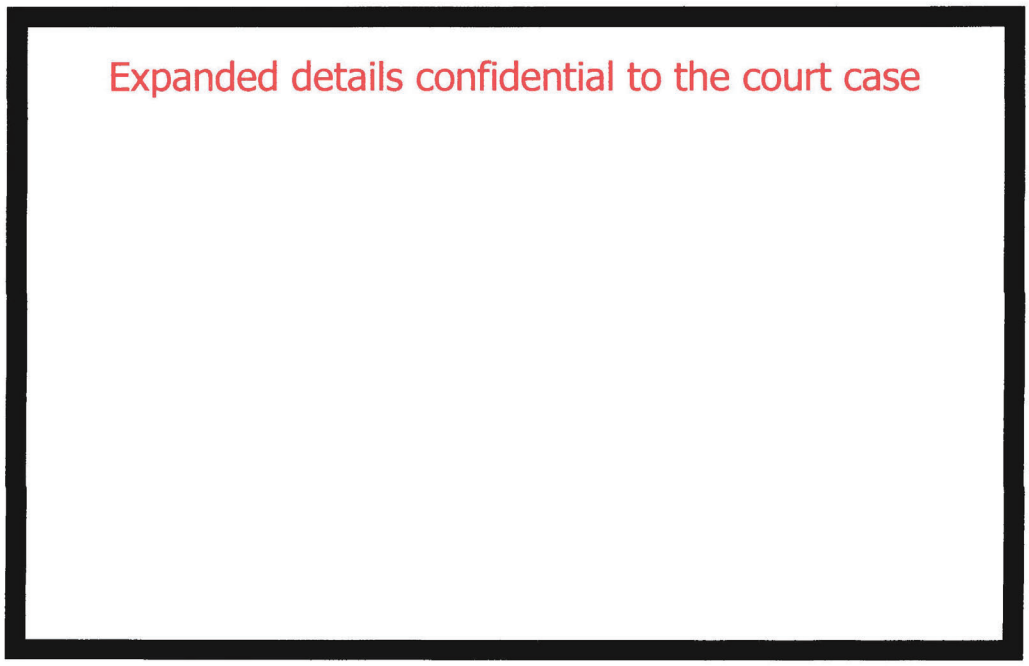
2)

Expanded details confidential to the court case



j. She has not had any psychotic symptoms since, nor is there any indication in the extensive records from the resultant investigation that she has ever had a psychotic condition.

1)



2)

3)

k. *Both Dr. Fong and Dr. Wirshing opined and concur that cannabis can and does induce psychosis in some individuals, and that this is what occurred with Ms. Spejcher on that evening of 5/28/18.*

1) According to Dr. Timothy Fong, Professor of Psychiatry Director, UCLA Addiction Psychiatry Fellowship Steering Committee, UCLA Cannabis Research Initiative: "a person can show significant signs of cannabis intoxication and impairment with low blood levels of THC (<50 ng/ml), especially in naïve or inexperienced users…The peak of cannabis intoxication and impairment isn't likely to occur when blood levels of THC are the highest. This is because THC impairment is related to THC levels and activity in the brain, not the blood. THC levels in the brain dissipate quickly after consumption but blood levels of THC take several hours to decline. This means a blood test would find a small amount of THC in the blood of occasional smokers after a few hours…It has been my clinical experience and it is my opinion that individuals who have had no prior history of delusions or hallucinations can develop psychotic symptoms from a single session of consuming THC, especially when smoking a high concentrated THC product. Prior history of being diagnosed with a psychotic disorder is not a risk factor to developing psychotic symptoms while intoxicated with THC. The development of psychotic symptoms such as delusions and hallucinations while intoxicated with THC is more likely related to total dose and concentration of THC consumed, along with user experience, how rapid THC was absorbed (smoking is the fastest) and genetic vulnerabilities to develop psychotic reactions to THC…It has been my clinical experience that individuals with no prior history of violence can consume cannabis (even during one session) and then proceed to commit acts of physical violence to themselves and to others. Even a single dose of cannabis may cause impairments in behavioral control that lead to impulsive, violent behavior. Physical violence can occur during states of cannabis intoxication, particularly when someone feels threatened, anxious or altered due to the psychotropic effect of cannabis. In my clinical experience, I have seen dozens of cases of cannabis intoxication that have resulted in suicide attempts, severe self-injurious behaviors like cutting and unprovoked physical violence toward others… Ms. Spejcher's blood level taken at the hospital was approximately 13 ng/ml. Her THC level in her blood at the time of the stabbings would have been higher but, most certainly, she would have had THC present in her body at the time of the incident. The most relevant issue is not what her THC blood levels were at the time of the incident but how intoxicated, altered and psychotic she was from the THC she ingested." Letter from Timothy Fong, dated 12/2/21, 1-3

2) Dr. Wirshing also opined that Ms. Spejcher experienced a marijuana induced psychotic reaction. Spejcher Affidavit of William Wirshing, MD dated 6/24/21, 5

FINDINGS AND OPINIONS

1. **At the time of the alleged crimes, Ms. Spejcher qualified for the following DSM-5-TR diagnosis (APA, 2022, p. 126-127) F12.959, Cannabis-Induced Psychotic Disorder, without use disorder.**

Cannabis-Induced Psychotic Disorder

- DSM-5-TR Criteria (APA, 2022, p. 126) are based on:

A. Presence of one or both of the following symptoms:
   1. Delusions.
   2. Hallucinations.

B. There is evidence from history, physical examination, or laboratory findings of both (1) and (2):
   1. The symptoms of Criterion A developed during or soon after substance intoxication or withdrawal or after exposure to or withdrawal from a medication.
   2. The involved substance/medication is capable of producing the symptoms in Criterion A.

C. The disturbance is not better explained by a psychotic disorder that is not substance/medication-induced. Such evidence of an independent psychotic disorder could include the following:

   The symptoms preceded the onset of the substance/medication use; the symptoms persist for a substantial period of time (e.g., about 1 month) after the cessation of the acute withdrawal or severe intoxication; or there is other evidence of an independent non-substance/medication induced psychotic disorder (e.g., a history of recurrent non-substance/medication-related episodes).

D. The disturbance does not exclusively occur during the course of a delirium.

E. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

- The severity rating would be 4 (most severe).

The DSM-5-TR notes (APA, 2022, p. 129) that "Cannabis-induced psychotic disorder may develop shortly after high-dose cannabis use and usually involves persecutory delusions, marked anxiety, emotional lability, and depersonalization. The disorder usually remits within a day but in some cases may persist longer."

Sincerely,

Kris Mohandie, Ph.D., ABPP
Licensed Psychologist

Docket No. DEA-1362

ROBERT A. SCHWARTZ
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Certified Specialist, Criminal Law,
The State Bar of California
Board of Legal Specialization

March 26, 2024

[redacted]

Re: Application of Bryn Spejcher for Audiology License

I am writing on behalf of my client Bryn Spejcher. As her attorney for the past five years, I have learned a great deal about her character, integrity, intelligence, and devotion for helping those who are hearing impaired. Nearly deaf since childhood, Bryn overcame many obstacles to excel in academics, sports, music and dance. She graduated from Washington University School of Medicine in St. Louis, earning a degree in audiology and receiving the Max Goldstein Award for achievement and dedication bestowed by the school faculty.

The incident giving rise to the criminal charge of involuntary manslaughter was a horrible tragedy, but does not diminish the exemplary manner she has conducted her life with. She was seeing a young man who was a heavy marijuana user. She was an inexperienced user of marijuana, and previously became high only once, and then with a negligible effect on that occasion. On May 28, 2018, Bryn inhaled from the marijuana bong belonging to Chad O'Melia. She felt no effect at all. About 30 minutes later he pressured her into smoking from the bong a second time, saying that this time it would be "more intense." After inhaling this second time she immediately felt something seriously wrong. She began coughing uncontrollably, and felt dizzy. Shortly after laying down on a sofa in the decedent's residence, she began experiencing delusions and hallucinations. Soon thereafter she began stabbing Mr. O'Melia, causing injuries that led to his death. When Sheriff's deputies were summoned to the scene, their body worn camera captured Bryn stabbing herself repeatedly in the neck, even after she was given commands to drop the knife, and after she was struck four times by a Taser gun fired by one of the deputies. Only after she was struck nine times by a mental-tipped baton from another deputy was the knife dislodged from her hand. This latter action probably saved her life.

[redacted]

Four authoritative experts interviewed Bryn and the evidence in the case. The conclusions reached were unanimous: that Bryn was in a cannabis induced psychosis at the time of the killing and had no cognitive or conscious awareness of her actions. Moreover, one of the defense experts, Dr. William Wirshing, a renowned authority on the subject of psychosis, concluded that the reaction that Bryn experienced from the second inhale of the decedent's marijuana bong was not "predictable." None of the experts found any evidence that Bryn suffered from an underlying mental illness or impairment. What came out at trial is that there is a documented link as confirmed in peer-reviewed medical literature between marijuana and psychosis, and marijuana and violence. It should be noted that the marijuana purchased by the decedent from a marijuana delivery service within a week of the stabbing incident was of a high potency (31.8%) variety. and that the delivery service web site for this strain of marijuana came with a warning: "Caution high tolerance users only."

It was for these and similar reasons that the judge who heard the trial sentenced Bryn to probation and no time in custody.

Let me know if you need any further information.

Very truly yours,

Robert A. Schwartz,
Attorney at Law

RAS:brc

Docket No. DEA-1362

CLINICAL
PHARMACOLOGY
SERVICES

03/26/24

[redacted]

RE: Bryn Spejcher, AuD

Dear Board Members,

I would like to take this opportunity to express my support for Bryn Spejcher, AuD to apply for her licensure to practice Audiology in the State of [redacted] Bryn is a very professional, skilled, and talented audiologist. I am on the faculty at the University of South Florida's College of Pharmacy and Medicine and practice in Tampa, Florida. My specialty is Clinical Pharmacology and Toxicology. I have worked directly with several of the Florida Department of Health's professional regulatory boards, providing expert testimony and technical support, to promote quality patient care practice and patient safety. I fully appreciate your board's commitment to serving the patients and practitioners in your state.

I have become extremely familiar with an unfortunate experience that took place in Bryn's life in 2018. While a young practicing Audiologist in Thousand Oaks California, she became the subject of a cruel and deceptive action by an individual who gave her high-potency marijuana, without her knowledge or awareness. The substance produced a severe psychotic reaction, something we are seeing more frequently in emergency medicine and toxicology. The development of severe psychiatric adverse side effects (debilitating anxiety, paranoia, catatonia, hallucinations, and psychosis) is associated with the ingestion of marijuana and other cannabinoid agents following the agricultural evolution of marijuana strains (high potency) occurring simultaneously with changing regulations and increased accessibility to these substances. The outcome of her event was tragic, but it bears no

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reflection of who Bryn is as an individual or as a healthcare provider. The reaction that occurred produced a state of dissociation and detachment from the reality of her surroundings and cognitive processes. The facts of the situation have been reviewed in detail and her altered mental state and diagnosis were agreed upon by me and multiple national experts, each of reaching the same conclusion, that she experienced cannabis-induced psychosis because of the substance given to her on that date.

There is so much to learn and educate the public about the risks associated with high-potency marijuana (i.e., cannabinoids). However, it would also be heartbreaking to see this single event, that was perpetrated on her, preclude her ability to make a positive impact on patients with audiology-related clinical needs. Her character, exemplary training, and professional practice performance should stand on their merit and support her ability to attain licensure and continue to practice in the future. Bryn grew up with severe hearing loss but did not let that stand in her academic or professional aspirations. She overcame significant obstacles and excelled every step of the way in academics, varsity sports, and ultimately during graduate school earning the highest honors possible. She is a remarkable young woman and has so much to give to the hearing-impaired community.

Based on my professional training and experience in patient care, cannabinoid research, and medication safety, I would strongly support her ability to continue her career as a healthcare practitioner specializing in Audiology. Thank you for your review and consideration of this recommendation. I extend the offer to present to you and to be a resource for the [redacted] to answer any questions that you may have related to this matter.

Sincerely,

Dr. Daniel E. Buffington

Dr. Daniel E. Buffington
Clinical Pharmacology & Toxicology

DOCKET NO. DEA-1362

SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF VENTURA

PUBLIC COURT INFORMATION SHEET

Name: Spejcher, Bryn P **DOB:** 1/25/91 **Case #:** 2018018798 F A **Case Status:** Appeal

Alias Type	Name	DOB	Entered
Alias	Spejcher, Bryn Pearce	01/25/1991	06/02/2018 05:40 pm

Violations

Cnt	S/A	Off Lvl		Plea	Dt Plea	Disposition	Dt Dispo
1		F	192(b) PC	Not Guilty	09/27/23	Found guilty by Jury	12/01/23
	05/28/18		Involuntary Manslaughter by An Unlawful Act				
	1	F	12022(b)(1) PC	Denied	09/27/23	Stricken	01/23/24
	05/28/18		S/A-Enh - Use Of Deadly Weapon				
	2	F	1192.7(c)(8) PC	Denied	09/27/23	Stricken	01/23/24
	05/28/18		S/A Serious Felony				
	3	F	4.421(a)(1) CRC	Denied	09/27/23	Stricken	01/23/24
	05/28/18		S/A - Enh - Crime involved Great Violence				
	4	F	4.421(b)(1) CRC	Denied	09/27/23	Stricken	01/23/24
	05/28/18		S/A - Enh - Defendant Has Engaged in Violent Conduct				
	5	F	4.421(a)(2) CRC	Denied	09/27/23	Stricken	01/23/24
	05/28/18		S/A - Enh - Armed With and Used a Weapon				

Sentence

Dt Sentence	Sentence	Disposition
01/23/24	Restitution	Active
01/23/24	Restitution	Active
01/23/24	Restitution	Active
01/23/24	Restitution	Active
01/23/24	Restitution	Active
01/23/24	36 Month(s) Probation	Active
02/26/24	Restitution	Active
03/13/24	Special Program	Active
03/13/24	40 Hour(s) Direct Work	Completed

Fiscal

Component	Due	Balance
Fees	$920.00	$870.00
Victim Restitution	$47,919.28	$47,919.28
VR Interest	$498.89	$498.89
Case Total:	$49,338.17	$49,288.17

Probation

Probation Type: Formal

End Date: 01/23/27 **Term:** 36 Month(s)

Probation Conditions/Deferred Entry Conditions

Dt Ordered	Condition
01/23/24	You are to obey all laws, city, county, state and federal.
	You shall not use or possess any narcotics, dangerous drugs, controlled substances, marijuana or paraphernalia unless prescribed.
	You shall not knowingly associate with any person who is using or trafficking in any controlled substance, including marijuana.

SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF VENTURA

PUBLIC COURT INFORMATION SHEET

Name: Spejcher, Bryn P **DOB:** 1/25/91 **Case #:** 2018018798 F A **Case Status:** Appeal

Probation Conditions/Deferred Entry Conditions

Dt Ordered	Condition
01/23/24	You shall not alter, adulterate, nor attempt in any manner to falsify any bodily fluids submitted for the determination of the presence of controlled substances, including marijuana.
	You will hereby consent to any tests to determine the presence of controlled substances, including marijuana, at any time by a peace officer or probation officer.
	Now consent to a search of your person, vehicle, residence, business, or any other personal or real property under your control for controlled substances, including marijuana and related paraphernalia, by a peace officer or probation officer at any time, with or without a search warrant, warrant of arrest, or reasonable cause.
	You shall not use or possess any marijuana, cannabis or their psychoactive ingredients in any form or quantity, or any paraphernalia for their use (hereafter collectively referred to as "marijuana").
	Now consent to a search of your person, vehicle, residence, or any other personal or real property under your control, by a peace officer or probation officer at any time, with or without a search warrant, warrant of arrest, or reasonable cause.
	You are to pay victim restitution of $29,808.69 to Sean O'Melia with the right to credit for amounts paid by other responsible persons.
	Pursuant to Penal Code sections 1214(b) and 1202.4(f)(3)(G) restitution shall include interest, at the rate of 10% per annum, that accrues as of the date of sentencing, unless otherwise specified by order of the court.
	Pursuant to Penal Code sections 1214(b) and 1202.4(i) the restitution order shall be enforceable as if the order were a civil judgment.
	Pursuant to Government Code § 50050: At the expiration of the three-year period after sentencing, unclaimed money representing restitution collected on behalf of victims shall be deposited in the California State Restitution Fund.
	You are directed to pay victim restitution payable to Sean O'Melia . The amount is to be determined by further order of the Court, as investigated by Probation, with the right to credit for amounts paid by other responsible persons.
	Pursuant to Penal Code sections 1214(b) and 1202.4(f)(3)(G) restitution shall include interest, at the rate of 10% per annum, that accrues as of the date of sentencing, unless otherwise specified by order of the court.
	Pursuant to Penal Code sections 1214(b) and 1202.4(i) the restitution order shall be enforceable as if the order were a civil judgment.
	Pursuant to Government Code § 50050: At the expiration of the three-year period after sentencing, unclaimed money representing restitution collected on behalf of victims shall be deposited in the California State Restitution Fund.
	You are to pay victim restitution of $4,360.80 to Vinicius Oliviera with the right to credit for amounts paid by other responsible persons.
	Pursuant to Penal Code sections 1214(b) and 1202.4(f)(3)(G) restitution shall include interest, at the rate of 10% per annum, that accrues as of the date of sentencing, unless otherwise specified by order of the court.
	Pursuant to Penal Code sections 1214(b) and 1202.4(i) the restitution order shall be enforceable as if the order were a civil judgment.
	Pursuant to Government Code § 50050: At the expiration of the three-year period after sentencing, unclaimed money representing restitution collected on behalf of victims shall be deposited in the California State Restitution Fund.
	You are to pay victim restitution of $12,749.79 to Steven Bruchner with the right to credit for amounts paid by other responsible persons.
	Pursuant to Penal Code sections 1214(b) and 1202.4(f)(3)(G) restitution shall include interest, at the rate of 10% per annum, that accrues as of the date of sentencing, unless otherwise specified by order of the court.
	Pursuant to Penal Code sections 1214(b) and 1202.4(i) the restitution order shall be enforceable as if the order were a civil judgment.
	Pursuant to Government Code § 50050: At the expiration of the three-year period after sentencing, unclaimed money representing restitution collected on behalf of victims shall be deposited in the California State Restitution Fund.

SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF VENTURA

PUBLIC COURT INFORMATION SHEET

Name: Spejcher, Bryn P **DOB:** 1/25/91 **Case #:** 2018018798 F A **Case Status:** Appeal

Probation Conditions/Deferred Entry Conditions

Dt Ordered	Condition
01/23/24	You are directed to pay victim restitution payable to Steven Bruchner . The amount is to be determined by further order of the Court, as investigated by Probation, with the right to credit for amounts paid by other responsible persons. Pursuant to Penal Code sections 1214(b) and 1202.4(f)(3)(G) restitution shall include interest, at the rate of 10% per annum, that accrues as of the date of sentencing, unless otherwise specified by order of the court. Pursuant to Penal Code sections 1214(b) and 1202.4(i) the restitution order shall be enforceable as if the order were a civil judgment. Pursuant to Government Code § 50050: At the expiration of the three-year period after sentencing, unclaimed money representing restitution collected on behalf of victims shall be deposited in the California State Restitution Fund.
03/13/24	Court orders probation term PAPO1 ; Obey All Laws deleted. You must report to the Probation Agency, 800 South Victoria Avenue, Ventura, California, Criminal Justice Center (Sheriff's Building) Room A, Second Floor. Report immediately after leaving court or upon release from custody. Bring this form with you. You must comply with the following terms and conditions: 1. Be under the supervision of a probation officer and report as directed. 2. Maintain regular employment as approved by the probation officer. 3. Not leave your county of residence for more than 72 hours or change your residence without prior approval by your probation officer. You shall not leave the State of California without prior permission of your probation officer. If you are on Felony Formal Probation, then the following applies: "You waive extradition to the State of California from any jurisdiction in or outside the United States where you may be found. You further agree that you will not contest any effort by any jurisdiction to return yourself to the State of California". 4. You shall participate in any treatment program as designated by your probation officer including no treatment . You shall authorize release of information between your probation officer and any treatment program designated above. 5. You shall maintain a residence/location with a street address or other dwelling as approved by your probation officer. 6. You shall not use any fictitious names or attempt to change your name unless by legal means and you shall notify your probation officer immediately upon initiating a name change. 7. Upon the request of any peace officer, you shall show identification with your true name, true date of birth, and current address. You shall pay a fine of $300.00 to the State Restitution Fund. The defendant hereby consents to a search of person, vehicle, residence, business, or any other personal or real property under the defendant's control at any time by any law enforcement officer or probation officer, with or without a search warrant, warrant of arrest, or reasonable cause, to determine the presence of any of the items prohibited under these terms, or evidence of any of the behaviors prohibited under these terms. You shall not own, possess, have under your custody or control, or have immediate access to, any weapon, including but not limited to firearms, pellet or BB guns, chemical weapons, a replica of any weapon, a conductive electrical device, or ammunition. Court orders probation term PAA4 ; not use or possess alcoholic beverages deleted. You shall submit to and complete tests of your breath, blood, or urine when requested by a peace officer or probation officer for alcohol. Court orders probation term PATRT ; evidence based treatment progarm deleted. Court orders probation term PAP1 ; Obtain individual psychotherapy deleted. You shall take prescribed medications as ordered by treating physician. Court orders probation term PADW ; 40 hours direct work deleted. You must attend weekly sessions of domestic violence counseling with an approved provider for a period of no less than one year, keep all appointments and pay program fees. You must complete 52 sessions within 55 weeks. A list of approved program providers is available through the probation department. Comply with the provisions of any valid restraining or injunctive order.

SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF VENTURA

PUBLIC COURT INFORMATION SHEET

Name: Spejcher, Bryn P **DOB:** 1/25/91 **Case #:** 2018018798 F A **Case Status:** Appeal

Probation Conditions/Deferred Entry Conditions

Dt Ordered	Condition
03/13/24	Bring proof of enrollment and attendance in Domestic Violence classes, Community Service hours and proof of reporting to your probation officer.
	You shall provide buccal swab samples, right thumb print, and palm prints pursuant to Section 296(a)(1) of the Penal Code.
	You shall have no contact with Sean O'Melia or his family .
	You shall not own, possess, or have immediate access to any dangerous weapons, firearms, ammunition or oleocapsicum pepper spray.
	You shall authorize submission of progress reports to the Probation Officer upon request. You shall pay a fee to the program for the costs of the counseling according to your ability to pay. You shall cooperate with the program in their financial assessment of your ability to pay. In the event that you are unable to make financial arrangements with an approved Domestic Violence Program you are ordered to immediately report to the Superior Court Collection Division (Collections), Room 205, for an assessment of your financial status. If Collections determines that you are able to pay for the counseling program, you must comply with the program's payment plan. If you disagree with Collections' determination that you are able to pay for the counseling, you must immediately request a hearing in court, at which time the court will consider Collections' written report and recommendation along with any evidence you present.
	The Court finds you have the ability to pay a total amount of $300.00 to the Ventura County Women's Shelters. This amount is payable at the rate of :
	a) $200.00 to: Interface Children and Family Services Battered Women's Shelter- 4001 Mission Oaks Blvd., Suite I, Camarillo, CA 93012-5156.
	b) $100.00 to: The Coalition to End Family Violence Battered Women's Shelter, 1030 N. Ventura Rd. Oxnard, California 93030.
	Each of these payments must be made by 03/14/25 . You are to provide proof of all payments to your probation officer.
	You shall pay a fee of $500.00 to the State Domestic Violence Fund.
	The court orders probation extended to 01/23/27 .

Sentence Modifications

Date Ordered	Description
01/23/24	No jail sanction imposed by court.

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FROM:
Bryn Spejcher
217 Edgebrook Drive
Bloomingdale, IL 60108

TO:
Drug Enforcement Admin.
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152
(Docket No. DEA-1362)

9/18/2024

Drug Enforcement Administration

Attn: Hearing Clerk/OALJ

8701 Morrissette Drive

Springfield, Virginia 22152

Subject: Notice of Appearance re" Docket No. DEA-1362

Dear Crystal Washington:

Please take notice that Phillip Drum, PharmD is available to appear in the matter of the Drug Enforcement Administration (DEA) on the notice of proposed rule-making to transfer marijuana from schedule I of the Controlled Substances Act (CSA) to schedule III of the CSA (Docket No. DEA-1362).

(A) I am an "interested person" as well as a "person adversely affected or aggrieved" by the proposed rule. The rescheduling would place the dispensing of marijuana for medical purposes as my responsibility as a California board certified pharmacist who is responsible for protecting the public from the hazards of controlled substances. I received by doctorate from the University of California – San Francisco (UCSF) and have been a licensed pharmacist in two states (CA and IL) in good standing for over 38 years. I have been an Oncology Pharmacist, and have been an instructor of Pharmacology at multiple schools of Pharmacy (UCSF, Touro University, UOP), Medical School (UCLA), Nursing Schools (Cal State Domiguez Hills, Samuel Merritt College, Touro University) and Podiatric Medicine (Samuel Merritt College). I have been a researcher and an educator of the influence of marijuana on driving, including as a speaker for Drug Recognition Expert (DRE) instructors, been appointed as the only pharmacist by Governor Gavin Newsom to a 3-year, state-wide CHP Impaired Driving Task Force required by California Senate Bill 94, provided education programs to multiple public settings including a presentation on "Marijuana-impaired Driving: what the data show" at the 2019 North American Cannabis Summit.

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.).

This proposed change in terms of rescheduling marijuana, without FDA-approved indication of use for marijuana poses specific challenges to my professional code of ethics. As a CS-III product, marijuana products need an FDA-approved package insert listing medical indication for use, scientific evidence of the benefits, exceeding the risks, of use in the approved indication, the appropriate dosage for various patient populations (age, pregnancy status, metabolic and clearance status, etc), potential adverse effects along with the incidence of occurrence, standard concentrations of active ingredients, storage requirements and clinically relevant drug interactions. Dispensing these products without such information pose a safety risk and inability of a pharmacist to provide required patient education about the safe use of their medicine. Another concerning feature is the contamination risk of the marijuana plant. This material is recognized by state labs and scientific reports to possess bacteria, fungi, pesticides and heavy metals that could pose a risk to the patient and pharmacy staff. The pharmacy environment would be at risk for with cross contamination in a time in which pharmacies that compound intravenous

materials are held to much higher sterility standards. The risk of these non-approved particles (bacteria, fungi, heavy metals, pesticides) have been seen in state regulated products, resulting in numerous recalls, across multiple states with a document death occurring of a California cancer patient from the exposure of his own medical marijuana product through DNA analysis of the offending agent. This poses a particular high risk to immune compromised, pediatric, and pregnant patients that pharmacists are commonly in contact with in both hospitals and community settings. Workers in the marijuana industry have reported exposures to infectious and hazardous materials along with allergenic risks.

As a citizen of the State of California, I was one of only two medical professionals (the other an addiction MD) on the California Highway Patrol (CHP) Impaired Driving Task Force. I was involved in the drafting of 31 recommendations to reduce the incidence of marijuana impaired driving and educate the public. I am one of the country's experts on the impact of marijuana on driving I am versed on the library of scientific literature on this subject including the current studies assessing the impact of marijuana use on operating motor vehicles, and the incidence of marijuana impaired driving following marijuana legalization in both the US and Canada. The cost to the American public of marijuana legalization has been a topic that is frequently ignored when discussing rescheduling of marijuana. Poly-drug driving (not only alcohol alone impaired driving) is an increasing cause of driving fatalities and must be addressed. There is no documented acceptable alcohol blood level when combine with marijuana in a driver.

(C) (State briefly the position of the person with regard to the particular objections or issues.).

For a medication in the US to be deemed a CS III substance, an FDA-approved indication along with the package inert be generated supporting the use of that agent including information on the dosing in various populations, pharmacokinetics, pharmacodynamics, scientific evidence for the approval, known drug interactions, incidence of adverse effects and proper storage. None of this information for marijuana has been performed by the FDA for the combination of the 100+ active cannabinoids found in marijuana, unlike the package insert currently available for the single cannabinoid products - dronabinol and cannabidiol. Until a package insert is made available by the FDA, marijuana remaining as a CS I substance is best for public safety. A risk evaluation and mitigation strategies (REMS) program could be utilized to determine a possible medical indication while monitoring for mental health disorders, pregnancy, other risks and benefits based on a scientific approach.

Prior to recommending any rescheduling of marijuana, which will increase access and use, the prudent approach is to first protect the public. This would include tightening regulations and creating new laws regarding marijuana impaired driving and educating the public on the associated risks. I have spent the past 12 years working on this area of public policy and have applied my extensive pharmaceutical knowledge to informing the government of California, as well as, law enforcement, state and federal law makers responsible for drug impaired driving legislation across the United States and internationally. Due to the unique pharmacokinetic and pharmacodynamics of marijuana, public safety from impaired drivers requires an approach used in our countries to demonstrate the seriousness of drug impaired drivers. A national zero tolerance law for impairing substances in a driver must be implemented before federally rescheduling marijuana.

All notices to be sent pursuant to this appearance should be addressed to:

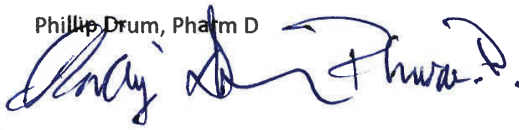
Phillip Drum, Pharm D

789 Condor Dr

Martinez, California 94553

Respectfully yours,

Phillip Drum, Pharm D



Evidence areas of concern/issues:

Evidence of Contaminants:

Cannabis use and fungal infections in a commercially insured population, United States, 2016, CDC K Benedict https://wwwnc.cdc.gov/eid/article/26/6/19-1570_article

Metagenomic analysis of medicinal Cannabis samples; pathogenic bacteria, toxigenic fungi, and beneficial microbes grow in culture-based yeast and mold tests – K McKernan et al F1000Research; https://f1000research.com/articles/5-2471/v1

Silvey B, et al "Occupational exposure to particulate matter and volatile organic compounds in two indoor cannabis production facilities" Ann Work Exp Health 2020 64 No 7, 715-727

CA:

"California recalls cannabis vape many months after it was told of contamination", LA Times 6/26/2024 by Paige St. John - https://archive.is/e80m4

Cannabis recalls and safety notices – Dept of Cannabis Control - https://cannabis.ca.gov/resources/cannabis-recalls-and-safety-notices/

CO:

"Recalls increase for tainted marijuana, as the industry calls for a study" CPR News 1/16/2024 by Ben Markus - https://www.cpr.org/2024/01/16/tained-marijuana-recalls-increase-for-colorado-cannabis-industry/

Med Health and Safety Advisories form the Colorado Dept of Revenue – 2024 health and Safety advisories - https://sbg.colorado.gov/med/health-and-safety-advisories

Health and Safety Advisory: Slow Burn Farms LLC - https://drive.google.com/file/d/1Uj3uNUyGnvolRlMByGqrAZpk68KVUdhF/view

MA:

"Former marijuana company employees raise concerns about HEKA growing practices", Western Maas News 12/14/2022, K Burnell https://www.westernmassnews.com/2022/12/14/former-marijuana-company-employees-raise-concerns-about-heka-growing-practices/

ME:

"Close to half of Maine's medical cannabis may contain pesticides, mold, officials say" https://www.pressherald.com/2023/09/21/close-to-half-of-maines-medical-cannabis-may-contain-pesticides-mold-officials-say/

Marijuana Impaired Driving Issues:

Cannabis use among drivers in fatal crashes in Washington state before and after legalization, January 2020 https://aaafoundation.org/cannabis-use-among-drivers-in-fatal-crashes-in-washington-state-before-and-after-legalization/

Marijuana-impaired driving: a report to congress DOT NHTSA July 2017 https://www.nhtsa.gov/sites/nhtsa.gov/files/documents/812440-marijuana-impaired-driving-report-to-congress.pdf

"Cannabis legalization and detection of tetrahydrocannabinol in injured drivers." JR Brubacher, et al NEJM 2022:386:148-56.

Oral fluid roadside analysis: pilot program – phase II January 2021. Michigan State Police. Sims et al https://www.michigan.gov/-/media/Project/Websites/msp/reports/phase_ii_oral_fluid_report.pdf?rev=911dc2c7042d444eb8918395a2211915

"Cannabis-involved traffic injury emergency department visits after cannabis legalization and commercialization" D Myran et al JAMA Network Sept 2023

Needs prior to Rescheduling to protect public:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/018651s029lbl.pdf

Senate Bill 94 (2017) – CHP repot to the legislature impaired driving task force report https://www.chp.ca.gov/ImpairedDrivingSite/Documents/Senate_Bill_94.pdf

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Martinez, CA 94553

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Drug Enforcement Administration
Attn: Administrator (Docket No DEA-1362)
8701 Morrissette Drive
Springfield, Virginia 22152

09/24/24 X RAYED

Cannabis Law PA
ATTORNEYS AT LAW

Judith D. Cassel
(717) 703-0804
jdcassel@hmslegal.com

Micah R. Bucy
(717) 703-0813
mrbucy@hmslegal.com

501 Corporate Circle, Suite 302, , Harrisburg, PA 17110 Phone: 717.703.0804 www.cannabislawpa.com

September 20, 2024

VIA EMAIL
Drug Enforcement Administration, Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152
nprm@dea.gov

Re: Schedules of Controlled Substances: Rescheduling of Marijuana, Docket No. DEA-1362; **NOTICE OF APPEARANCE**

Dear Sir or Madam:

Please take notice that the undersigned, Judith D. Cassel and Micah R. Bucy of Cannabis Law Pa ("Cannabis Law"), will appear at the hearing being held on December 2, 2024 at Army Navy Drive, Arlington, VA 22202 in the above-captioned rulemaking proceeding. We respectfully request permission to provide testimony at this hearing.

Cannabis Law is a Pennsylvania-based firm that represents and advises dozens of clients in the cannabis law space. The attorneys at Cannabis Law represent grower/processors, dispensaries, laboratories, clinical registrants, industry stakeholders, and patients to make the Pennsylvania, Ohio, Maryland, New York, New Jersey, and other states, medical marijuana programs better suited for all program participants. Additionally, Cannabis Law attorneys have actively supported the rescheduling of marijuana to eliminate unnecessary barriers for patients, with serious medical conditions, seeking to be treated with medical marijuana.

Cannabis Law does not object to the rescheduling of marijuana from Schedule I to Schedule III and requests the opportunity to speak at the hearing in support of its rescheduling.

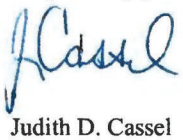
Specifically, Cannabis Law supports the rescheduling of marijuana because it would reduce cumbersome barriers and penalties faced by businesses selling marijuana and eliminate discriminatory and conflicting practices in federal housing assistance, employment, and custody matters. The rescheduling is a step in the right direction and will allow medical cannabis treatments, and the corresponding research into them, to flourish.

All notices to be sent pursuant to this appearance should be addressed to:

Judith D. Cassel and Micah Bucy
Cannabis Law Pa
501 Corporate Circle, Suite 302
Harrisburg, PA 17110

Thank you for your time and attention to this matter, please do not hesitate to contact our office if you should have any questions.

Respectfully yours,



Judith D. Cassel
Micah R. Bucy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501 Corporate Circle, Suite 302
Harrisburg, PA 17110
Drug Enforcement Administration,
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152

Drug Enforcement Association of Federal Narcotics Agents (DEAFNA)

Drug Enforcement Administration
Attn: Honorable Anne Milgram, Administrator
870 I Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA–1362 September 20, 2024

Honorable Administrator Milgram-

As the organization who represents retired and active Drug Enforcement Administration (DEA) Agents and additional DEA employees, again both retired and active, the Drug Enforcement Association of Federal Narcotics Agents (DEAFNA) is keenly situated to be identified as interested persons at a hearing on the matter related to Docket No. DEA-1362 concerning the rescheduling of Marijuana from Schedule I to Schedule III of the Controlled Substances Act. As an interested party adversely affected by this proposed change, we respectfully request a hearing to present evidence demonstrating that marijuana does not meet the criteria for rescheduling.

Specifically, we intend to present factual evidence and expert testimony showing that marijuana fails to satisfy the five key criteria established by the FDA for determining if a substance has a currently accepted medical use:

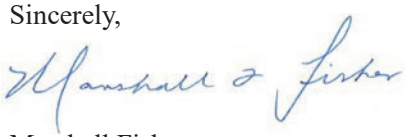
- Known and reproducible chemistry: Unlike pharmaceutical drugs, marijuana's chemical composition is highly variable and not standardized.
- Adequate safety studies: Recent research linking marijuana use to increased risks of psychosis and mental illness raises serious safety concerns that warrant further investigation.
- Well-controlled efficacy studies: The limited studies cited by the FDA to justify rescheduling are flawed and insufficient to demonstrate efficacy for medical use.
- Expert acceptance: Major medical organizations like the American Psychiatric Association have stated that marijuana can worsen certain psychiatric conditions, indicating a lack of expert consensus on its medical utility.
- Widely available scientific evidence: There is insufficient high-quality scientific data to conclusively establish marijuana as medicine, and medical experts do not agree on its therapeutic value.

We believe this evidence demonstrates that marijuana does not meet the statutory requirements for rescheduling to Schedule III at this time.

In addition, as stated above, DEAFNA is comprised of retired and active DEA agents, who unquestionably understand this issue from every perspective. In fact, DEA agents are the only federal employees whose sole mission since 1973 has been to enforce the controlled substances laws and regulations of the United States. We are adamantly opposed to any intentional move that we predict will have such a drastically negative and permanent impact on public safety and health. We respectfully request the opportunity to present these facts and expert opinions in greater detail at a hearing on this matter.

Thank you for your consideration. Please let me know if you require any additional information regarding our standing as an interested party or the evidence we intend to present.

Sincerely,



Marshall Fisher
President Drug Enforcement Association of Federal Narcotics Agents (DEAFNA)
marshallfisher@rocketmail.com

Outlook

[EXTERNAL] Docket No. DEA-1362: Schedules of Controlled Substances: Rescheduling of Marijuana - Request to testify at hearing

From Eric Foster <eric@m4mmunited.org>
Date Fri 9/20/2024 1:01 PM
To NPRM <NPRM@dea.gov>
Cc Jodeci Gonzalez <jodeci@m4mmunited.org>; Roz McCarthy <roz@m4mmunited.org>

1 attachment (958 KB)
M4MM Rescheduling 2024 -9-20-24.pdf;

Good afternoon.

My name is Eric Foster, I am National Policy Director for Cannabis and Hemp for Minorities for Medical Marijuana. Minorities for Medical Marijuana, Inc. (M4MM) is the country's largest community based non-profit advocacy organization in the Commercial Cannabis and Hemp industry sectors The organization was established in May 2016 and currently has 27 state chapters throughout the USA, 4 international chapters, and 3 HBCU chapters locations. M4MM's mission is focused on providing advocacy outreach, research and training as it relates to social equity, social justice, public policy and health & wellness in the cannabis industry. M4MM is dedicated to helping minorities navigate this new marijuana industry, as it relates to diversity, equity, and inclusion, with intentionality, policy, and broad economic considerations.

I am writing to request an opportunity to provide testimony on behalf of Minorities for Medical Marijuana at the December 2, 2024 hearing with respect to the proposed rescheduling of marijuana into schedule III of the Controlled Substances Act. We at Minorities for Medical Marijuana (M4MM) advocate for rescheduling marijuana to Schedule V under the CSA Rescheduling Administrative review and rulemaking period. The following points below highlight the rationale for a Schedule V designation, addressing the DEA's and the Department of Health and Human Services' (HHS) procedures and the eight-step process identified in 21 U.S.C. 811.

Key Schedule V Proposition Points

1. **Lower Potential for Abuse**:
   - **Relative to Schedule III**: Marijuana has a lower potential for abuse compared to substances in Schedule III. The abuse potential of marijuana is lower than that of many substances currently classified in higher schedules, making Schedule V a more appropriate classification.
   - **Comparative Data**: Evidence shows that marijuana is associated with fewer severe health outcomes compared to drugs in Schedules I-III, supporting a lower scheduling designation to reflect its lower risk profile.
2. **Currently Accepted Medical Use**:
   - **Widespread Medical Acceptance**: Marijuana is recognized for its medical use in numerous states across the U.S., demonstrating its efficacy in treating conditions like chronic pain, nausea, and more. This acceptance aligns with the requirements for Schedule V, which includes drugs with accepted medical uses.
   - **Scientific Evidence**: Multiple studies and clinical trials have documented the therapeutic benefits of marijuana, reinforcing its status as a drug with accepted medical use.
3. **Limited Dependence Liability**:
   - **Physical and Psychological Dependence**: Marijuana's potential for physical and psychological dependence is relatively low, fitting the criteria for Schedule V. The mild withdrawal symptoms observed further support this lower scheduling.

- **Comparison with Schedule IV**: The potential for dependence on marijuana is less than that of Schedule IV substances, which supports its placement in Schedule V where drugs have an even lower potential for abuse and dependence.

4. **Public Health and Safety**:
   - **Safety Profile**: The safety of marijuana when used under medical supervision is well-established, with fewer severe adverse effects compared to higher-scheduled substances. This aligns with the requirements for Schedule V, which include safety under medical supervision.
   - **Regulatory Controls**: Rescheduling marijuana to Schedule V would maintain necessary regulatory controls while allowing broader access for medical use, ensuring public health and safety are protected.
5. **Economic and Social Impacts**:
   - **Positive Community Impact**: Rescheduling to Schedule V could significantly benefit minority communities by creating more opportunities in the legal cannabis industry, fostering economic growth, and reducing disparities.
   - **Research Opportunities**: Lowering the scheduling to V would facilitate more extensive research into marijuana's therapeutic potentials, potentially leading to new medical products and treatments.
6. **Compliance with International Obligations**:
   - **Treaty Compliance**: Rescheduling marijuana to Schedule V can be done while ensuring compliance with international treaty obligations. This balance allows for domestic regulatory flexibility without compromising international commitments.

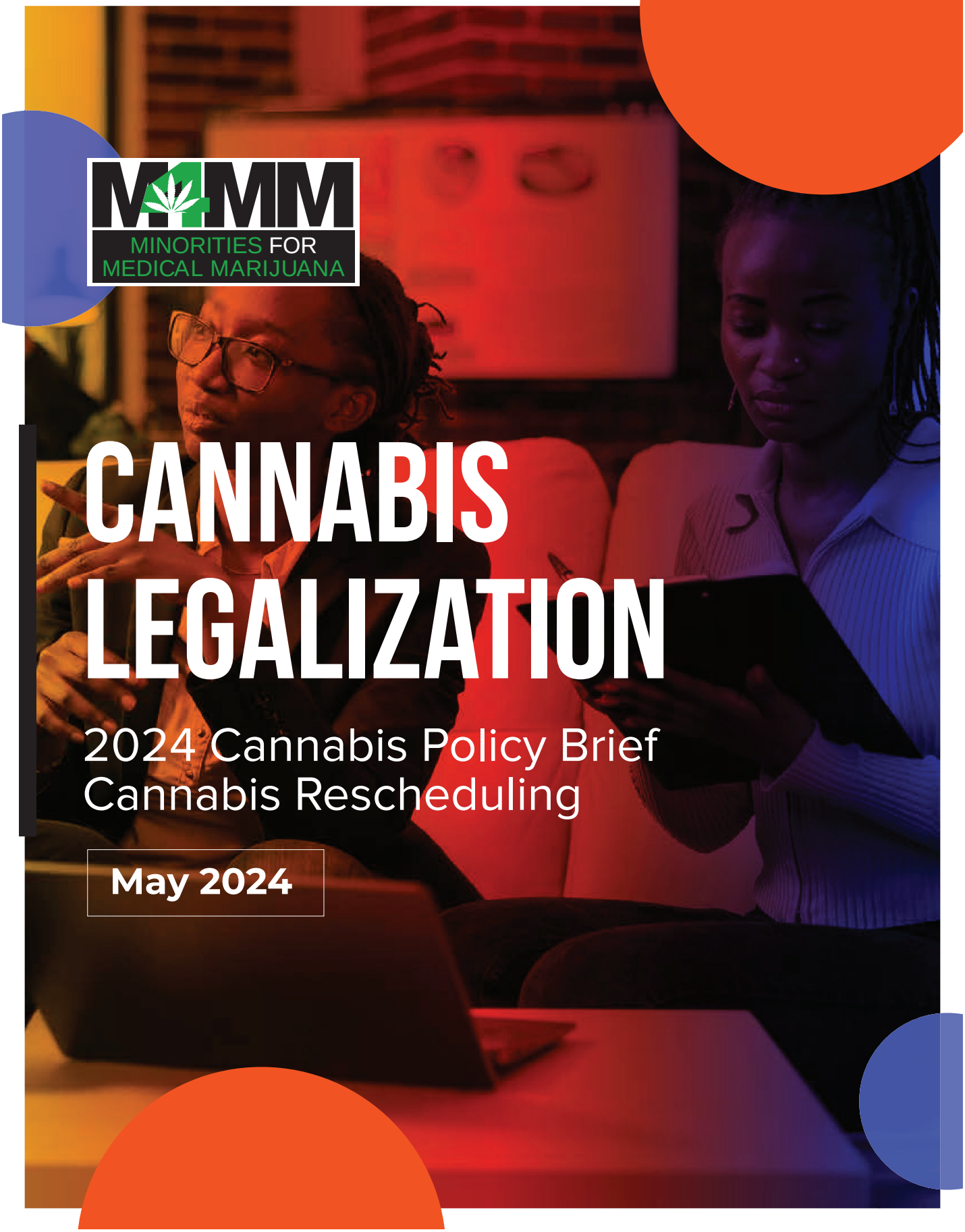
Minorities for Medical Marijuana strongly recommend rescheduling marijuana to Schedule V, which is supported by its lower potential for abuse, recognized medical use, limited dependence liability, and manageable public health risks. This change would facilitate broader access for medical purposes while maintaining appropriate regulatory controls, benefiting public health and supporting economic growth, particularly in minority communities. Schedule V also provides for the widest latitude for implementation and application of an expanded Blumenauer Amendment for protection of the State level Cannabis programs.

We at Minorities for Medical Marijuana request an opportunity to testify to provide our rationale for rescheduling to Schedule V, our recommendations on how to craft the detailed structure of regulatory jurisdictional relationships between Federal Agencies and State-Level Medical Cannabis regulatory agencies and State-Level statutory/constitutional laws and why we believe that the administrative process only allows for rescheduling options and that descheduling must be conducted via Congressional action.

Please feel free to contact me at 248-996-5553 or email me at eric@m4mmunited.org regarding details for participating in the December 2, 2024 hearing. Thank you in advance for your consideration.

Sincerely,

Eric Foster
National Policy Director for Cannabis & Hemp Policy
Minorities for Medical Marijuana
Cellphone: 248-996-5553
www.m4mmunited.org



MINORITIES FOR MEDICAL MARIJUANA

CANNABIS LEGALIZATION

2024 Cannabis Policy Brief
Cannabis Rescheduling

May 2024

TALKING POINTS FOR PUBLIC COMMENT PERIOD: ADVOCACY FOR RESCHEDULING MARIJUANA TO SCHEDULE V

Members of Minorities for Medical Marijuana (M4MM) who advocate for rescheduling marijuana to Schedule V can use the following talking points during the federal rulemaking public comment period. These points highlight the rationale for a Schedule V designation, addressing the DEA's and the Department of Health and Human Services' (HHS) procedures and the eight-step process identified in 21 U.S.C. 811.

KEY TALKING POINTS

1. LOWER POTENTIAL FOR ABUSE:

- **Relative to Schedule III:** Marijuana has a lower potential for abuse compared to substances in Schedule III. The abuse potential of marijuana is lower than that of many substances currently classified in higher schedules, making Schedule V a more appropriate classification
- **Comparative Data:** Evidence shows that marijuana is associated with fewer severe health outcomes compared to drugs in Schedules I-III, supporting a lower scheduling designation to reflect its lower risk profile

2. CURRENTLY ACCEPTED MEDICAL USE:

- **Widespread Medical Acceptance:** Marijuana is recognized for its medical use in numerous states across the U.S., demonstrating its efficacy in treating conditions like chronic pain, nausea, and more. This acceptance aligns with the requirements for Schedule V, which includes drugs with accepted medical uses
- **Scientific Evidence:** Multiple studies and clinical trials have documented the therapeutic benefits of marijuana, reinforcing its status as a drug with accepted medical use

3. LIMITED DEPENDENCE LIABILITY:

- **Physical and Psychological Dependence:** Marijuana's potential for physical and psychological dependence is relatively low, fitting the criteria for Schedule V. The mild withdrawal symptoms observed further support this lower scheduling
- **Comparison with Schedule IV:** The potential for dependence on marijuana is less than that of Schedule IV substances, which supports its placement in Schedule V where drugs have an even lower potential for abuse and dependence

4. PUBLIC HEALTH AND SAFETY:

- **Safety Profile:** The safety of marijuana when used under medical supervision is well-established, with fewer severe adverse effects compared to higher-scheduled substances. This aligns with the requirements for Schedule V, which include safety under medical supervision
- **Regulatory Controls:** Rescheduling marijuana to Schedule V would maintain necessary regulatory controls while allowing broader access for medical use, ensuring public health and safety are protected

5. ECONOMIC AND SOCIAL IMPACTS:

- **Positive Community Impact:** Rescheduling to Schedule V could significantly benefit minority communities by creating more opportunities in the legal cannabis industry, fostering economic growth, and reducing disparities
- **Research Opportunities:** Lowering the scheduling to V would facilitate more extensive research into marijuana's therapeutic potentials, potentially leading to new medical products and treatments

6. COMPLIANCE WITH INTERNATIONAL OBLIGATIONS:

- **Treaty Compliance:** Rescheduling marijuana to Schedule V can be done while ensuring compliance with international treaty obligations. This balance allows for domestic regulatory flexibility without compromising international commitments

EIGHT-STEP PROCESS FOR RESCHEDULING (21 U.S.C. 811)

To reschedule marijuana to Schedule V, the following eight factors must be considered

1. Potential for Abuse: Marijuana has a low potential for abuse relative to substances in Schedule IV.
2. Scientific Evidence of Pharmacological Effect: Evidence supports marijuana's efficacy in treating various medical conditions.
3. Current Scientific Knowledge: There is extensive scientific knowledge about marijuana's effects and medical uses.
4. History and Pattern of Abuse: The abuse pattern of marijuana is less severe than that of higher-scheduled drugs.
5. Scope and Significance of Abuse: The overall public health impact of marijuana abuse is relatively low.
6. Risk to Public Health: Marijuana poses a lower risk to public health compared to higher-scheduled substances.
7. Dependence Liability: Marijuana's potential for dependence is low, supporting a Schedule V classification.
8. Immediate Precursor: Marijuana is not an immediate precursor of any substance already controlled under the CSA

CONCLUSION

Rescheduling marijuana to Schedule V is supported by its lower potential for abuse, recognized medical use, limited dependence liability, and manageable public health risks. This change would facilitate broader access for medical purposes while maintaining appropriate regulatory controls, benefiting public health and supporting economic growth, particularly in minority communities.

Members of Minorities for Medical Marijuana are encouraged to support this initiative and participate in the public comment period to ensure their perspectives are included in the decision-making process.

TALKING POINTS FOR PUBLIC COMMENT PERIOD: SUPPORT FOR RESCHEDULING MARIJUANA TO SCHEDULE III

INTRODUCTION

Members of Minorities for Medical Marijuana (M4MM) who support the recommendation to reschedule marijuana to Schedule III can use the following talking points during the federal rulemaking public comment period. These points highlight the scientific, medical, and regulatory reasons for supporting the rescheduling initiative as outlined in the DEA Rescheduling Draft (Docket No. DEA-1362; A.G. Order No. 5931-2024).

KEY TALKING POINTS

1. LOWER POTENTIAL FOR ABUSE:

- **Scientific Consensus:** The Department of Health and Human Services (HHS) has determined that marijuana has a relatively lower potential for abuse compared to Schedule I and II substances. This aligns with the broader scientific understanding that while marijuana is widely used, its abuse potential is significantly less than that of drugs like heroin and cocaine
- **Attorney General's Conclusion:** Based on HHS's scientific and medical findings, marijuana does not warrant control under Schedule I due to its lower abuse potential and dependence liability

2. ACCEPTED MEDICAL USE:

- **Medical Utility:** Marijuana has a currently accepted medical use in the United States, as recognized by the HHS. It is used in state-authorized medical programs to treat conditions such as chronic pain, nausea, and other debilitating symptoms
- **Clinical Evidence:** There is substantial clinical evidence supporting the medical benefits of marijuana, which justifies its placement in Schedule III where drugs with accepted medical uses and lower abuse potential are classified

3. SAFETY UNDER MEDICAL SUPERVISION:

- **Regulatory Controls:** Rescheduling marijuana to Schedule III will impose appropriate regulatory controls to ensure its safe use under medical supervision. This will include specific guidelines for manufacturing, distributing, and prescribing marijuana, thereby minimizing risks associated with its medical use
- **Public Health Benefits:** By rescheduling marijuana, patients will have better access to a substance that can effectively manage their symptoms while ensuring that the necessary safeguards are in place to prevent misuse and abuse

4. ECONOMIC AND SOCIAL IMPACTS:

- **Support for Minority Communities:** Rescheduling marijuana to Schedule III can have positive economic and social impacts, particularly for minority communities.

1. Health Equity: Rescheduling marijuana to Schedule III acknowledges its medicinal value and will ensure that individuals from minority communities have improved access to alternative treatment options for various health conditions.

2. Community Impact: Rescheduling marijuana can positively impact the overall well-being of minority communities by providing access to safer and regulated products, reducing the reliance on illicit markets, and promoting responsible use through medical oversight.

3. Criminal Justice Reform: Rescheduling marijuana would help alleviate the disproportionate impact of drug enforcement policies on minority communities at the state level, (depending upon state by state statutory law social justice reforms enacted as a response to rescheduling), leading to fairer treatment and reducing the number of individuals incarcerated for non-violent drug offenses.

4. Medical Benefits: Recognizing marijuana's medical use and rescheduling it to a lower category will facilitate further research into its benefits and potential as a treatment option for various ailments, benefiting individuals from minority groups who may disproportionately suffer from certain health conditions.

5. Cultural Considerations: Acknowledging the historical and cultural significance of cannabis in minority communities and recognizing its potential benefits through rescheduling reinforces the importance of cultural competence and inclusivity in health policy decisions.

- **Research and Development:** Rescheduling will facilitate more extensive research and development into marijuana's therapeutic potentials, leading to better medical products and treatments, which can benefit a broad range of patients

5. COMPLIANCE WITH INTERNATIONAL OBLIGATIONS:

- **Treaty Compliance:** Rescheduling marijuana to Schedule III will ensure that the United States remains compliant with international treaty obligations, balancing domestic regulatory needs with international commitments

6. INVITATION FOR PUBLIC COMMENTS:

- **Participatory Process:** The DEA is soliciting public comments on this proposed rulemaking. M4MM members are encouraged to participate actively in this process by submitting their comments and supporting the rescheduling initiative, ensuring that their voices and perspectives are considered

CONCLUSION

Rescheduling marijuana to Schedule III is a scientifically sound and medically justified step that acknowledges its therapeutic benefits while ensuring proper regulatory oversight. This move will benefit patients, support economic growth, particularly in minority communities, and align with both domestic and international regulatory standards.

M4MM POTENTIAL IMPLICATIONS FROM DHHS CRS REPORT, REVIEW OF RESCHEDULING RECOMMENDATION (DHHS), PROPOSED RULE (DEA), TALKING POINTS AND LETTERS OF SUPPORT FOR SCHEDULE III AND SCHEDULE V

Potential Implications of a Move to Schedule III – Congressional Research Services (CRS) Report on DHHS rescheduling recommendation

A change to Schedule III would mark a major shift in the federal government's policy on marijuana. For over 50 years, marijuana has remained on Schedule I. Violations of CSA law involving marijuana have resulted in criminal sanctions for thousands of offenders. There are many federal policy implications of such a shift, particularly because most states now have comprehensive medical marijuana programs. The following are selected federal policy implications if marijuana were to be rescheduled:

- Those who manufacture, distribute, dispense, and possess medical marijuana may now be able to do so lawfully (under the CSA).
- States' medical marijuana programs may now be able to comply with the CSA, and will still be subject to CSA/DEA criminal and regulatory control, federal public health laws such as the Federal Food, Drug, and Cosmetic Act, and agricultural laws such as the Agricultural Marketing Act of 1946.
- The scope of and demand for FDA oversight for medical marijuana and related products may grow considerably. In the short term, FDA may need to generate or update a substantial amount of technical information to clarify its regulatory approach to marijuana for relevant stakeholders. Given that marijuana is a complex substance containing various pharmaceutical components and is available to consumers in numerous formats, FDA may also need to consider long-term resource allocation to ensure that marijuana products consistently meet applicable regulatory standards.
- Marijuana producers and retailers would be able to deduct the costs of selling their product (e.g., payroll, rent, advertising) for the purposes of federal income tax filings.
- Those who use medical marijuana lawfully may now be eligible to (1) access public housing, (2) obtain immigrant and nonimmigrant visas, and (3) purchase and possess firearms. Those who use marijuana recreationally would still face restrictions in these areas.
- Researchers would face less strict regulatory controls in researching marijuana as a Schedule III controlled substance, which may in turn promote further research on marijuana.
- DEA would no longer set production quota limitations for marijuana.
- Those who use medical marijuana lawfully may contend with fewer barriers to federal employment and eligibility to serve in the military.

SUMMARY OF POSITIVE AND SUPPORTIVE CONCLUSIONS FOR RECOMMENDING MARIJUANA'S RESCHEDULING TO SCHEDULE III

The "Basis for the Recommendation to Reschedule Marijuana into Schedule III - HHS Report" presents several positive and supportive conclusions that justify the rescheduling of marijuana. Below is a detailed summary of these conclusions for distribution purposes:

POSITIVE CONCLUSIONS

1. LOWER ABUSE POTENTIAL COMPARED TO SCHEDULE I AND II SUBSTANCES:

- Marijuana has a lower potential for abuse relative to substances in Schedules I and II. Epidemiological data indicate that marijuana is associated with fewer severe adverse outcomes compared to substances like heroin and cocaine

2. CURRENTLY ACCEPTED MEDICAL USE:

- Marijuana is recognized as having a currently accepted medical use in the United States. This is based on widespread clinical experience by licensed healthcare providers operating under state-authorized medical marijuana programs. Conditions for which marijuana is used include chronic pain, nausea, and vomiting associated with chemotherapy, and anorexia associated with weight loss in AIDS patients
- The CAMU test, which considers both widespread medical use and scientific support, has been satisfied, further supporting the recommendation

3. SAFETY PROFILE:

- Marijuana has an acceptable safety profile when used under medical supervision for the indicated conditions. This was determined based on data from clinical studies, professional organization position statements, and state medical marijuana programs. The evidence suggests that the adverse effects are generally manageable and less severe compared to many Schedule I and II substances
- FDA-approved drug products containing dronabinol, a synthetic form of THC, demonstrate that controlled use of THC can be safe and effective for certain medical conditions

4. MODERATE OR LOW PHYSICAL DEPENDENCE:

- Marijuana may lead to moderate or low physical dependence or high psychological dependence. The withdrawal symptoms are relatively mild compared to substances like alcohol and tobacco. This supports a lower scheduling as the risk of severe dependence and associated harm is less

5. SCIENTIFIC AND MEDICAL SUPPORT:

- Various professional organizations and systematic reviews acknowledge the therapeutic potential of marijuana. For example, the American Medical Association and other health organizations have recognized its potential benefits for specific medical conditions and have called for more research to expand its medical applications

6. COMPARATIVE SAFETY AND ABUSE DATA:

- Comparative analyses show that marijuana has a lower incidence of severe adverse outcomes and a lower potential for abuse compared to other controlled substances. Data from multiple epidemiological databases consistently place marijuana in a lower ranking for adverse health effects compared to drugs like heroin and oxycodone

7. FEDERAL AND STATE-LEVEL RECOGNITION:

- The acknowledgment by federal agencies such as the FDA and NIDA, along with the widespread acceptance of medical marijuana programs at the state level, underscores the recognized medical utility and relative safety of marijuana

CONCLUSION

The recommendation to reschedule marijuana to Schedule III is supported by its lower potential for abuse compared to Schedule I and II substances, its accepted medical use, and its manageable safety profile under medical supervision. The mild nature of its withdrawal symptoms and the supportive stance of various medical organizations further justify its rescheduling. This change would facilitate more research and potentially expand the medical use of marijuana while maintaining appropriate controls to mitigate risks of abuse and dependence.

SUMMARY OF NEGATIVE AND UNCERTAIN CONCLUSIONS FOR RECOMMENDING MARIJUANA'S RESCHEDULING TO SCHEDULE III

The "Basis for the Recommendation to Reschedule Marijuana into Schedule III - HHS Report" outlines several negative and uncertain conclusions regarding the rescheduling of marijuana to Schedule III. Below is a summary of these conclusions for distribution purposes:

NEGATIVE CONCLUSIONS

1. LACK OF HIGH-QUALITY EVIDENCE:

- Many professional organizations and systematic reviews indicate that the evidence supporting the therapeutic benefits of marijuana is of low quality. For example, the American Academy of Neurology and the American Epilepsy Society both highlight insufficient scientific evidence to support the medical use of cannabis for neurologic disorders and epilepsy, respectively
- Studies often rely on synthetic THC rather than botanical marijuana, which limits the applicability of findings to real-world medical use of marijuan

2. PSYCHIATRIC RISKS:

- The American Psychiatric Association does not endorse cannabis as a medicine and notes its association with the onset of psychiatric disorders. This organization specifically recommends against its medical use due to the potential exacerbation of psychiatric conditions

3. PHYSICAL AND PSYCHOLOGICAL DEPENDENCE:

- Chronic use of marijuana can lead to both physical and psychological dependence. Symptoms of marijuana withdrawal, such as sleep difficulties, irritability, and decreased appetite, are relatively mild but do indicate a potential for dependence

4. ADVERSE EFFECTS:

- Common adverse effects reported include dry mouth, headaches, psychoactive euphoria, agitation, and palpitations. Severe adverse events, while uncommon, do occur and pose risks to patients

UNCERTAIN CONCLUSIONS

1. INCONSISTENT EFFICACY FINDINGS:

- Systematic reviews and clinical studies show mixed results regarding the efficacy of marijuana for various medical conditions. For example, while some evidence supports its use for pain, nausea, and vomiting, the findings are not consistent across all studies
- The potential benefits of marijuana in treating PTSD are based on observational studies with high risk of bias, making the findings less reliable

2. LACK OF FDA APPROVAL:

- Marijuana has not been approved by the FDA for any therapeutic indication. Its use is primarily driven by state-level medical marijuana laws rather than federal approval, leading to variability in quality and control of the substance

3. NEED FOR MORE RESEARCH:

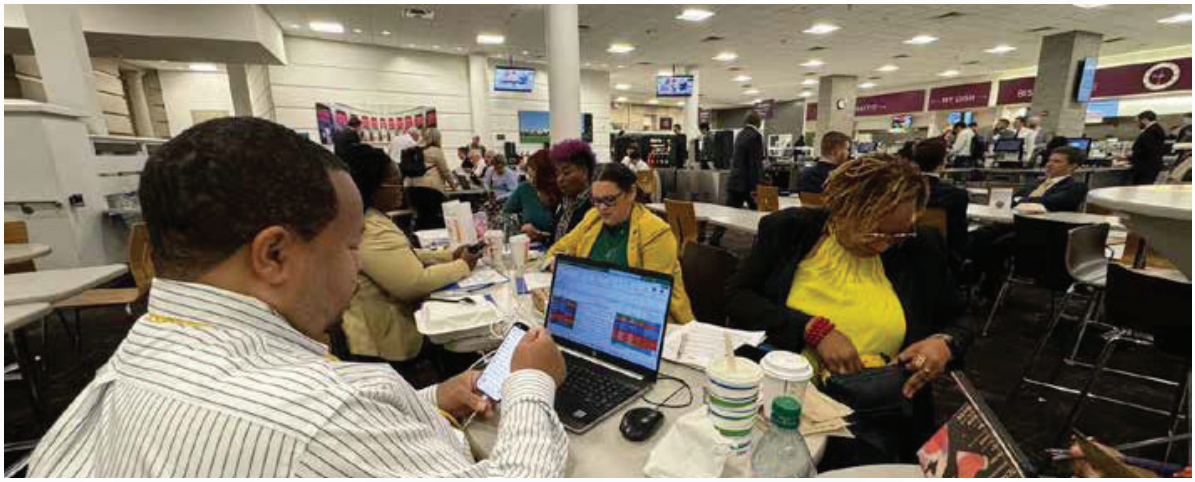
- Many professional organizations call for more rigorous research to better understand the long-term safety and efficacy of marijuana. The current restrictions on research due to its Schedule I status have limited the availability of high-quality clinical data

4. POTENTIAL FOR ABUSE:

- Although marijuana has a lower potential for abuse compared to substances in Schedules I and II, it still poses significant risks for nonmedical use and diversion. The abuse potential of marijuana necessitates careful consideration when rescheduling to ensure that it does not lead to increased misuse

CONCLUSION

While the recommendation to reschedule marijuana to Schedule III is based on some evidence of its medical benefits, the conclusions drawn in the HHS report highlight several negative and uncertain aspects that warrant caution. The mixed quality of evidence, potential for psychiatric risks, and physical dependence, along with the need for more comprehensive research, underscore the complexities involved in changing the scheduling status of marijuana.



SUMMARY OVERVIEW OF THE DEA RESCHEDULING DRAFT DOCUMENT: DOCKET NO. DEA-1362; A.G. ORDER NO. 5931-2024 - SCHEDULING NPRM 508

INTRODUCTION

This document outlines the proposal by the Attorney General to reschedule marijuana from Schedule I to Schedule III under the Controlled Substances Act (CSA). The recommendation is based on an evaluation by the Department of Health and Human Services (HHS) which found marijuana has a lower potential for abuse compared to substances in Schedules I and II, and it may lead to moderate or low physical dependence or high psychological dependence.

KEY FINDINGS AND RECOMMENDATIONS

1. POTENTIAL FOR ABUSE:

- **Evaluation by HHS:** Marijuana is associated with a high prevalence of use, but its abuse potential is lower than that of Schedule I and II substances such as heroin and cocaine. The abuse of marijuana may lead to moderate or low physical dependence and a low likelihood of severe psychological dependence
- **Attorney General's Conclusion:** Based on HHS's scientific and medical findings, marijuana does not warrant control under Schedule I due to its lower abuse potential and dependence liability

2. MEDICAL USE:

- **Currently Accepted Medical Use (CAMU):** HHS has recognized that marijuana has a currently accepted medical use in the United States. This conclusion is based on its widespread use by licensed healthcare practitioners in state-authorized medical programs and credible scientific support for at least one medical use
- **Recommendation for Schedule III:** The recommendation to transfer marijuana to Schedule III rather than Schedule II is due to its lower potential for abuse and dependence compared to substances in those schedules

3. EPIDEMIOLOGICAL DATA:

- **Comparison with Other Substances:** Marijuana ranks lower on various measures of harm compared to Schedule I and II substances. Despite high availability and use, it produces fewer serious outcomes than these more strictly controlled drugs

  Health Outcomes: Epidemiological data suggest that while marijuana use is prevalent, it does not produce serious health outcomes comparable to those of substances in Schedules I and II

4. REGULATORY IMPACT:

- **International Treaty Obligations:** Rescheduling marijuana to Schedule III will allow the United States to continue meeting its international treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances with additional regulatory controls as needed

  Economic Considerations: Rescheduling may have significant economic impacts, including effects on federal taxes, research, and development investments in the pharmaceutical industry. The DEA is seeking comments on these potential economic impacts as part of the rulemaking process

CONCLUSION

The proposed rulemaking to reschedule marijuana to Schedule III is based on a comprehensive review of scientific, medical, and epidemiological data by HHS. The recommendation acknowledges marijuana's lower potential for abuse and dependence compared to Schedule I and II substances and its recognized medical use in the United States. The DEA is inviting public comments to further inform this rulemaking process

MINORITIES FOR MEDICAL MARIJUANA

2024 POLICY BRIEF CONTRIBUTORS

ROZ MCCARTHY

M4MM FOUNDER/CEO

ERIC FOSTER

M4MM NATIONAL DIRECTOR FOR CANNABIS AND HEMP POLICY


MMM
MINORITIES FOR
MEDICAL MARIJUANA

September 22, 2024
Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

24 Cambell Shore Rd
Gray,ME 04039

Subject: Notice of Appearance Docket No. DEA-1362

Dear Sir or Madam:

Please take notice that Derek J Shirley will appear in the matter of: Docket No. DEA-1362.

Mr. Shirley has an interest as a medical marijuana patient whose life has been adversely affected by prohibitive legislation of marijuana, including having a felony for 4 ounces of cannabis and restricted access to medications in certain regions of the country.

Mr. Shirley believes that as someone with ADHD, his ADA rights are being withheld from him since he exclusively uses marijuana to address his medical conditions. However, he is unable to use the medication he chooses (that was prescribed by a medical professional) in certain regions of the United States as well as in housing situations where it is generally prohibited, which directly discriminates against him as a person with disabilities, an act that is prohibited by the Americans with Disabilities Act of 1990. Also the fact their are cannabis companies that are billionaires while approximately 35,000 people are still locked in jail for cannabis related charges.

Derek Shirley believes the best remedy to this discrepancy would be the entire descheduling of Cannabis on a federal level or come up with a "cannabis bill of rights" so everyone can have equal rights to cannabis in this country and leaving the details of taxation, regulation, and distribution to be managed on a state-wide level

All notices to be sent pursuant to this appearance should be addressed to:

Derek Shirley
24 Cambell Shore Rd
Gray,Maine, 04039

Respectfully yours, Derek J. Shirley

AFNA

Association of Federal Narcotics Agents
www.afna.org

Drug Enforcement Administration
Attn: Honorable Anne Milgram, Administrator
870 I Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA–1362 September 23, 2024

Honorable Administrator Milgram-

As the organization who represents retired and active Drug Enforcement Administration (DEA) Agents and additional DEA employees, again both retired and active, the Drug Enforcement Association of Federal Narcotics Agents (DEAFNA) is keenly situated to be identified as interested persons at a hearing on the matter related to Docket No. DEA-1362 concerning the rescheduling of Marijuana from Schedule I to Schedule III of the Controlled Substances Act. As an interested party adversely affected by this proposed change, we respectfully request a hearing to present evidence demonstrating that marijuana does not meet the criteria for rescheduling.

Specifically, we intend to present factual evidence and expert testimony showing that marijuana fails to satisfy the five key criteria established by the FDA for determining if a substance has a currently accepted medical use:

- Known and reproducible chemistry: Unlike pharmaceutical drugs, marijuana's chemical composition is highly variable and not standardized.
- Adequate safety studies: Recent research linking marijuana use to increased risks of psychosis and mental illness raises serious safety concerns that warrant further investigation.
- Well-controlled efficacy studies: The limited studies cited by the FDA to justify rescheduling are flawed and insufficient to demonstrate efficacy for medical use.
- Expert acceptance: Major medical organizations like the American Psychiatric Association have stated that marijuana can worsen certain psychiatric conditions, indicating a lack of expert consensus on its medical utility.
- Widely available scientific evidence: There is insufficient high-quality scientific data to conclusively establish marijuana as medicine, and medical experts do not agree on its therapeutic value.

We believe this evidence demonstrates that marijuana does not meet the statutory requirements for rescheduling to Schedule III at this time.

In addition, as stated above, DEAFNA is comprised of retired and active DEA agents, who unquestionably understand this issue from every perspective. In fact, DEA agents are the only federal employees whose sole mission since 1973 has been to enforce the controlled substances laws and regulations of the United States. We are adamantly opposed to any intentional move that we predict will have such a drastically negative and permanent impact on public safety and health. We respectfully request the opportunity to present these facts and expert opinions in greater detail at a hearing on this matter.

Thank you for your consideration. Please let me know if you require any additional information regarding our standing as an interested party or the evidence we intend to present.

Sincerely,

M Marshall Fisher

Marshall Fisher
President Drug Enforcement Association of Federal Narcotics Agents (DEAFNA)
marshallfisher@rocketmail.com

AFNA
P.O. Box 2801
Ashburn, VA 20146

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Thinking of You
FREEDOM STATION

Drug Enforcement Administration,
Attn: Administrator, 8701 Morrissette
Drive, Springfield, Virginia 22152

22152-108001

9/23/24

To: Drug Enforcement Administration,
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive,
Springfield, VA 22152
nprm@dea.gov

CC by US mail: US Attorney General Merrick Garland
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington DC 20530

From: Rev. Bryan A. Krumm, CNP
733 Monroe St. NE
Albuquerque, NM 87110
(505) 414-8120

Re: Amended Request for Hearing

Pursuant to 21 CFR § 1316.47: I, Rev. Bryan Krumm, CNP, hereby request a hearing in the matter of: [Docket No. DEA–1362; A.G. Order No. 5931–2024] Schedules of Controlled Substances: Rescheduling of Marijuana. This is an amended request to the request mailed 6/20/24.

On December 8, 2020, I filed a Rescheduling Petition for Cannabis with the DEA, requesting that Cannabis be removed from Schedule 1 of the Controlled Substances Act. This was 6 days after Cannabis had been removed from the most restrictive status of the Single Convention Treaty. Because I never received a response from the DEA, I re-filed the petition with the current administration on July 14, 2021. DEA acknowledged receipt of the petition on July 21, 2021 and

stated "your petition is currently under review". After waiting for over a year, I sent a letter requesting the status of my rescheduling petition and on September 23, 2022 DEA responded to me, claiming that they they must first request a review by the FDA before acting on my rescheduling petition, something that should have been initiated when my rescheduling petition became under review..

Because the DEA has a long history of unreasonable delays regarding rescheduling petitions and because DEA had failed to request a review by the FDA in over a year, I filed a complaint with the Court of Appeals for the DC Circuit, asking the court to intervene in order to protect the health, safety and welfare of American Citizens. Unfortunately my complaint was dismissed because I filed more than 30 days after DEA's response. I was forced to wait for the FDA to complete a review of Cannabis before a determination would be made on my rescheduling petition. A review that legally should have begun nearly 2 years earlier.

However, on October 6, 2022, President Joseph Biden released a statement asking the Secretary of Health and Attorney General to expedite review of how Cannabis was scheduled under federal law, and on August 29, 2023 HHS officially notified DEA that Cannabis should be moved to Schedule 3 of the CSA.

When it became clear that DEA was again delaying action on these rescheduling petitions, even after FDA and HHS recommended that Cannabis be moved to Schedule 3, on February 2, 2024 I filed a petition for Writ of Mandamus

asking the Court of Appeals to order DEA to fulfill it's legal obligation to reschedule Cannabis. Although the Court denied my request April 19, 2024, on April 30, 2024 the DEA announced that Attorney General Merrick Garland had ordered them to move Cannabis to Schedule 3 of the Controlled Substance, Act, 21 USC 801 et seq., in compliance with the clear statutory language of the CSA

This is not my first experience with DEA's use of delay as a tactic to prevent access to Medical Cannabis. On December 17, 2009, I filed a rescheduling petition requesting that Cannabis be removed from control under the Controlled Substances Act and that control of Cannabis be placed under control of the States. After nearly 7 years of delay, on August 12, 2016, the DEA settled that petition (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016/Proposed Rules 53767 - 53844). DEA has still not fully complied with the HHS recommendations from that settlement.

For decades the DEA has blocked the Medical Cannabis research they require in order to demonstrate "accepted medical use in the United States". Evidence of the ongoing efforts by the DEA to prevent relevant Medical Cannabis research is found in the DEA's own "Denial of Petition to Initiate Proceedings to Reschedule Marijuana". The FDA admitted that "notably, it is beyond the scope of this review to determine whether these data demonstrate that marijuana has a currently accepted medical use in the United States" However, The FDA did report that the eleven studies evaluated in their review showed positive signals that

marijuana may produce a desirable therapeutic outcome and has been shown to help chronic neuropathic pain, increase appetite in HIV, reduce spasticity in Multiple Sclerosis, produce bronchodilation in asthma, and reduce intraoccular pressure in glaucoma. (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016, 53792).

In his May 20, 2015 letter titled FDA Recommendations On The Scheduling Of Marijuana Under The Controlled Substances Act, to Karen DeSalvo (Acting Assistant Secretary for Health), Stephen Ostroff (Acting Commissioner of Food and Drugs) discussed 5 distinct areas of the federal regulatory system that have blocked efficient and scientifically rigorous research with marijuana and its constituents.

1. DEA has refused registration of additional cultivators of Cannabis for research.

2. PHS review is required for Cannabis research but not for other Schedule 1 substances.

3. DEA review of all research with Schedule 1 substances and registration requirements restrict research.

4. Certain Cannabis constituents have never been properly evaluated by HHS to determine if they should remain in Schedule 1.

5. DOJ/DEA and HHS need to reassess the legal and regulatory framework as applied to 1) assessment of abuse liability and 2) the assessment of

currently accepted medical use for drugs that have not been approved by the FDA.

Karen DeSalvo further substantiated the futility of the administrative process in her June 3, 2015 letter to Chuck Rosenberg, when she stated "Concerns have been raised about whether the existing federal regulatory system is flexible enough to respond to increased interest in research into the potential therapeutic uses of marijuana and marijuana derived drugs." (Federal Register/Vol. 81, No. 156/ Friday, August 12, 2016/Proposed Rules, 53768)

On December 2, 2020, the United States recommended that Cannabis be removed from the most restrictive status of the Single Convention Treaty and stated that Cannabis has proven medical value, declaring that "the legitimate use of a Cannabis preparation has been established through scientific research, and Cannabis no longer meets the criterion for placement in Schedule IV of the Single Convention". (Commission on Narcotic Drugs Reconvened sixty-third session Vienna, 2–4 December 2020. Statements following the voting on the WHO scheduling recommendations on cannabis and cannabis-related substances, p12)

The DEA has noted that Section 811 (d)(1) provides that where a drug is subject to control under the Single Convention, the DEA administrator (by delegation from the Attorney General) must "issue an order controlling such drug under the schedule he deems most appropriate to carry out such treaty obligations,

without regard to the findings required by [21 U.S.C. 811 (a) or 812 (b)] and without regard to the procedures prescribed by [21 U.S.C 811 (a) and (b)]……..DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing on that final determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings" Federal Register/Vol. 81, No. 156/ Friday, August 12, 2016, Page 53767-53768.

Therefore, based the medical and scientific findings of the FDA, the DEA is required to at least move Cannabis to a schedule 3 of the CSA. However, medical and scientific findings of the FDA are not required to determine that Cannabis should be removed from control under the CSA and regulated like alcohol and tobacco, in order to protect the health, safety and welfare of the American People. The safety of Cannabis was previously considered by the DEA. "In The Matter of Marijuana Rescheduling", DEA Docket No. 86-22, September 6, 1988, resulted in a finding that, "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man." Id. at pages 58-59. "The evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary, and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record." Id. At page 68

In comprehensive reviews conducted by the Federal Government on the use of smoked Cannabis, experts have consistently concluded that smoked Cannabis is safe and effective for medical use. "The evidence is perfectly clear that smoking is an outstanding route of administration….it's a very safe drug and therefore it would be perfectly safe medically to let the patient determine their own dose through the smoking route". See National Institutes of Health. Transcript of the NIH Workshop on the Medical Utility of Marijuana. Tab B, Deliberations of the Ad Hoc Group of Experts; February 19&20, 1997. (Ace-Federal Reporters, Inc., Cr66002.0) See also Joy, Janet E., Stanley J., Watson, and John A. Benson, Jr., (eds) Marijuana as Medicine: Assessing the Science Base,. (National Academy Press 1999). "Until a nonsmoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting".

Under the CSA, the Attorney General has the authority to reschedule a drug if he finds that it does not meet the criteria for the schedule to which it has been assigned. 21 U.S.C. 811(a) 16 (2); see also Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1133 (D.C. Cir.1994); Kuromiya v. United States, 37 F.Supp.2d 717,722 (E.D. Pa.1999) ("There are provisions by which the Attorney General may change the designation of a particular controlled substance, either to move it up, down, or off of the schedules.") (citing 21 U.S.C. 811). The Attorney

General has delegated this authority to the Administrator of the DEA ("Administrator"). See Alliance for Cannabis Therapeutics, 15 F.3d at 1133.

Cannabis is an ancient drug, not a new drug. It has been safely used as a medication for thousands of years and there has never been a death due to any toxic effects. Comprehensive study of legal medical Cannabis users in the Federal IND found only mild changes in pulmonary function associated with long term heavy use. No functionally significant attributable sequelae were noted in any other physiological system examined in the study, which included: MRI scans of the brain, pulmonary function tests, chest X-ray, neuropsychological tests, hormone and immunological assays, electroencephalography, P300 testing, history, and neurological clinical examination. (Russo et.al. 2002, "Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis") (see http://acmed.org/data/pdf/2002-01-1.pdf). There is no legitimate rationale either medically, scientifically, ethically or legally, not to exempt cannabis from control under the CSA and regulate it like alcohol and tobacco.

Cannabis has been accepted as having medical use by 46 States. Cannabis has also been legalized for recreational use by 24 States because it is safer than either alcohol or tobacco, both of which are exempted from control under the CSA. In order to protect the health, safety and welfare of the Citizens of these States and every State:

1. Any rules implemented to regulate cannabis in schedule 3 of the CSA must not interfere with rights of the States to implement programs regarding medical and recreational Cannabis for their citizens.
2. In order to protect the health, safety and welfare of all US citizens, medical patients from all States must be allowed to have protected access to Cannabis without undue restrictions being implemented.
3. Regulations must be developed to allow legitimate Cannabis businesses and their employees access to banking.
4. Due to the broad range of therapeutic applications, research into the therapeutic use of Cannabis must be encouraged and appropriately funded.
5. In order to ensure that Medical Cannabis Patients have affordable access to needed medication, insurance companies should be required to cover the cost of Cannabis prescriptions with reasonable or zero co-pays, commensurate with other medications within their formularies.
6. Because the medical use of Cannabis has been demonized and denied for nearly a century, continuing education programs must be developed to train Medical Providers appropriate prescribing practices for Cannabis.
7. Because the Veterans Administration has forbidden their providers from working with State Medical Cannabis Programs, educational inservices should

be developed to ensure that Veterans are receiving the highest standards of care, based on the best available scientific evidence.

8. In order to ensure these rules can be implemented properly, the Attorney General and DEA should exempt Cannabis from control under the CSA and allow it to be regulated by the States like alcohol and tobacco rather than moving Cannabis into Schedule 3, which could potentially limit medical access to Cannabis and cause harm to millions of Americans.

All notices to be sent pursuant to the proceeding should be sent to :

Rev. Bryan A. Krumm, CNP
733 Monroe St. NE
Albuquerque, NM 87110
(505) 414-8120
reeferdoc@hotmail.com

Electronically submitted to DEA at nprm@dea.gov

And to Atty General Merrick Garland via USPS priority mail at
U.S. Department of Justice at 950 Pennsylvania Avenue NW, Washington DC 20530

this 23’rd day of September, 2024

Rev. Bryan A. Krumm, CNP

September 23, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive,
Springfield, VA 22152

Subject: Notice of Appearance

Docket No. DEA-1362

Dear Hearing Clerk,

Please take notice that Jill Simonian, PharmD, will appear in the matter of The Proposed Rescheduling of Marijuana into Schedule III of the Controlled Substances Act.

A) As a pharmacist and president of the Pharmacists' Cannabis Coalition of California (PCCC), I am committed to providing safe and effective use of cannabis for medical therapy. Pharmacists are well established as the experts in medication management and are the most qualified and accessible healthcare professionals to guide patients with cannabis medicine.

B) On behalf of PCCC, I would like to respectfully submit our position in support of the rescheduling of cannabis to Schedule III of the Controlled Substances Act (CSA), and the designation of pharmacists, in collaboration with other specialized healthcare professionals, as the providers of medical cannabis therapy to ensure patient access to a pharmacist for the guidance of safe and effective medical cannabis use. While the prevalence of cannabis use continues to rise and the senior population is increasingly seeking medical cannabis therapy, patient access to a healthcare provider with expertise in cannabis medicine has not progressed at the same rate, and in fact, is nearly nonexistent. Botanical cannabis made available in pharmacies would provide patients not only access to consistent, safe, and standardized cannabis products, but also, importantly, the benefit of expertise from a knowledgeable pharmacist for counseling on dosing, drug interactions, and adverse effects. We support a novel framework for botanical cannabis manufacturing and distribution facilities with governmental oversight to ensure purity and consistency for provision to pharmacies.

C) Patients deserve safe, reliable, and affordable cannabis medicine and guidance from a trusted healthcare professional exclusive of an adult-use dispensary.

Respectfully,

All notices to be sent pursuant to this appearance should be addressed to:
Jill Simonian, PharmD
On behalf of Pharmacists' Cannabis Coalition of California (PCCC)
5034 Caminito Vista Lujo
San Diego, Ca 92130

TheDocApp

4055 1st Ave SW Naples, FL 34119
www.TheDocApp.com
(833) 665-3279

Pres. Nick Garulay Nick@TheDocApp.net
Jason Castro, IHC. JasonCastro@MyFloridaGreen.com

September 24, 2024

From: Jason Castro, Esq.
Inhouse Counsel,
The Doc App, Inc.,
d.b.a. My Florida Green

To: Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152
Email: nprm@dea.gov

Subject: Notice of Intention to Participate in DEA Hearing on Proposed Rescheduling of Marijuana (Docket No. DEA–1362)

Dear Administrator,

I, Jason K. Castro, am writing to formally notify you of my intention to participate in the upcoming hearing on December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

1. Interest in the Proceeding:

As In-House Counsel for The Doc App, Inc., doing business as My Florida Green, I represent a platform that serves over 41,000 medical marijuana patients in Florida. Over the past eight years, we have invested more than $2 million into building a compliant and patient-centric platform that empowers patients and doctors in navigating the complexities of medical marijuana treatment. Given the impact this rescheduling could have on both patients and providers, I intend to address critical issues related to federal mandates for data sharing, API access from dispensaries, and regulatory alignment.

2. Issues to be Addressed:

During the hearing, I plan to cover several important topics:

- **Federal Mandates for Data Access:** I will advocate for the federal government to mandate that states provide critical data to medical marijuana cardholders and grant platforms like ours access to API information from federally approved dispensaries. This would empower patients to make informed decisions and ensure compliance with state and federal laws.
- **The Role of The Doc App in Transforming Patient Care:** I will highlight how our platform offers detailed analytics on the efficacy of different strains and forms of marijuana, enabling patients to optimize their treatment. I will also discuss our efforts to enhance the system with real-time tracking of patients' 70-day rolling allotment, preventing unintentional overuse.
- **Regulatory Alignment:** I will address the challenges posed by the current patchwork of state and federal regulations and advocate for a more unified approach. This would reduce confusion for both patients and providers, streamline compliance, and improve the overall effectiveness of medical marijuana programs nationwide.

3. Position on the Issues:

While I support the rescheduling of marijuana to Schedule III, I believe it presents an opportunity to ensure that patients across the country have consistent and equitable access to the tools and data they need to manage their treatment effectively. Federal mandates on data sharing and API access would ensure compliance, improve care, and empower patients nationwide.

Thank you for the opportunity to participate in this hearing. Please confirm receipt of this notice and provide any additional instructions or requirements for participation.

Sincerely,

/s/ Jason K. Castro, Esq.

Jason K. Castro
Fla. Bar.: 118604
As: Inhouse Counsel
The Doc App, Inc.
d.b.a. My Florida Green

cc: Nicholas Garulay, President and CEO, The Doc App, Inc.

Aubree Adams
+719-250-5740
aubree@everybrainmatters.org
www.everybrainmatters.org

TO: U.S Department of Justice
Drug Enforcement Administration
Attn: Matthew Strait
Deputy Assistant Administrator
Diversion Control Division
8701 Morrissette Drive
Springfield, Virginia 22152

FROM: Aubree Adams
1909 N. Elizabeth Street
Pueblo, CO 81003

Date: September 25, 2024
RE: Docket No. DEA – 1362

Dear Deputy Matthew Strait,

Thank you for your email regarding my request for a hearing on the proposed rule to transfer marijuana from Schedule I to Schedule III of the Controlled Substances Act. I appreciate the opportunity to provide additional information.

In this letter, I have provided the information you requested that establishes me as an adversely affected person, along with links to resources.

My standing as an affected or aggrieved person:

My name is Aubree Adams. I am a concerned parent, advocate, and director of the nonprofit Every Brain Matters, I've seen firsthand the devastating impact cannabis can have on families. I'm from Pueblo, Colorado, and my teenage son became addicted to cannabis products shortly after legalization. He had easy access to these products at school and in our neighborhood. Even worse, neighbors involved him in selling their legally home-grown marijuana, putting his future at risk. This is the reality that too many parents and families are facing today.

As a parent, I've watched in agony as cannabis took a devastating toll on my son. He began experiencing symptoms of psychosis, like paranoia, delusions, and even hallucinations. His behavior became increasingly aggressive, both toward himself and others, and he eventually attempted to take his own life. Despite two psychiatric hospitalizations, interventions from the Department of Social Services, home-based therapy, and two inpatient treatment programs, I knew something had to change. I took him to Houston, Texas, in search of sustainable, long-term recovery to save his humanity and life. I couldn't stand by as Colorado's cannabis laws continued to enable the destruction of his mental and physical health.

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I not only witnessed the impact of cannabis on my son but also on my husband. His mental health began to deteriorate as he struggled with depression and panic attacks. In an attempt to cope, he turned to cannabis, specifically a flower with 24% THC, recommended by a marijuana shop in Pueblo, Colorado. While it initially numbed his pain, it soon made things worse, intensifying his depression and anxiety and leading to suicidal thoughts and auditory hallucinations. The toll this has taken on my family is heartbreaking and financially devastating. We had to sell our two homes. We lost all our equity. We are now just rebuilding our lives.

I was devastated by what was happening to my family. My husband's condition did not improve, and he eventually required an inpatient stay at a psychiatric hospital. For the safety of my sons and myself, we separated.

After three years of sobriety, my son tragically relapsed on Delta-8-THC and Delta-10-THC, products made legal under the 2018 Federal Farm Bill. His relapse led to a two-year estrangement from our family. When he finally reached out for help, he was suffering from symptoms of cannabinoid hyperemesis syndrome; he was painfully thin, constantly vomiting, and unable to eat.

During this marijuana nightmare, I met more and more families harmed by marijuana; these families and I developed a nonprofit called Every Brain Matters to advocate for families, provide education driven by science, and build family recovery resources, including support meetings. Our mission is to help families prevent, manage, or recover from a loved one's harmful cannabis use. We also advocate for change and more protections for our families with our project, The Voices of Marijuana Harms, which features the stories of the families harmed and a memorial of the people we have lost from the effects of marijuana.

As the United States moves forward with policies to expand access to ultra-potent cannabis products, it's crucial that we carefully consider the potential public health impacts and ensure that these decisions are grounded in science and safety. Today's industrialized marijuana products are so toxic that the industry loads them with sugary flavors to mask the poisonous taste. Our government allows the addiction-for-profit marijuana industry to promote using cannabis with false medical claims. At the same time, there are no marijuana detox facilities or insurance approved inpatient treatment centers that specialize in cannabis use disorder, cannabis-induced psychosis, and cannabinoid hyperemesis syndrome.

As this cannabis crisis continues to grow, I hear from more and more traumatized families blindsided by the predatory practices of the marijuana industry. Every day, 2 to 5 families join the Every Brain Matters community, desperate for help and solutions. They ask me, "Why is our government sacrificing our children's health on the cannabis altar when they should be protecting them?"

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I must tell them the hard truth: in the United States, money and politics have been prioritized over the health and safety of our children and families. But then I offer hope, sharing valuable recovery tools I've learned as a parent and a host mom for youth in recovery so they can survive this crisis even if their children do not.

It's heartbreaking to acknowledge that even if families do everything they can to prevent their loved ones from using cannabis, our communities and government policies enable them to continue to use. For many, the damage caused by high-potency THC is so severe that their kids or loved ones can no longer comprehend the extent of their illness or how to accept help. With no long-term treatment protocols for cannabis-induced psychosis, I teach families how to protect their own well-being, stay safe, and practice detaching with love, a painful but necessary process of letting go, hoping the consequences their children face will eventually lead them to recovery. Our government fails to understand that these people are trapped, living a hell of chronic psychosis and vomiting, desperately trying to self-medicate with drugs to numb their hallucinations and delusional and paranoid thoughts.

I've seen firsthand how government policies promoting marijuana enable our loved ones to destroy their mental and physical health. To combat this, I publish videos on our Every Brain Matters YouTube channel, sharing stories of families who are finding ways to survive this marijuana nightmare. My goal is to bring hope and sanity back into the conversation.

Rescheduling cannabis would have a devastating impact on America and the Every Brain Matters community. It would lead to increased cannabis use, driving more addiction, psychosis, and, ultimately, violence. Like my son and husband, more people will be harmed. The impact will be felt for generations to come.

We are living the disastrous consequences since the 2018 Farm Bill rescheduled hemp. California Governor Gavin Newsom is now trying to address the harm caused by this predatory industry. Hemp products, despite being marketed as safe, can be highly intoxicating and are especially dangerous to our youth. These products are causing great psychiatirc disorders and deaths by suicide. Every Brain Matters has covered this extensively in several podcasts:
Delta-8, Cardiac Arrest, Psychosis
The therapist Recommended CBD; Then I Found Delta-8-THC
Hemp Madness, What Parents Need to Know About Delta-8 and THC Variants

Rescheduling hemp has led people to falsely believe these products are harmless, and we can expect the same dangerous misconceptions and consequences if cannabis is rescheduled.

Sincerely,
Aubree Adams
Director, Parent, Advocate

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aubree@everybrainmatters.org
www.everybrainmatters.org

TO: U.S Department of Justice
Drug Enforcement Administration
Attn: Matthew Strait
Deputy Assistant Administrator
Diversion Control Division
8701 Morrissette Drive
Springfield, Virginia 22152

FROM: Aubree Adams
1909 N. Elizabeth Street
Pueblo, Colorado 81003

Date: September 25, 2024
RE: Docket No. DEA – 1362

Dear Deputy Matthew Strait,

Thank you for your email regarding my request for a hearing on the proposed rule to transfer marijuana from Schedule I to Schedule III of the Controlled Substances Act. I appreciate the opportunity to provide additional information that provides factual evidence and my expert opinion. I've includeed links to the resources.

Impacts of Rescheduling Cannabis

Rescheduling marijuana while ignoring the science will have devastating consequences for American families. It will fuel the addiction crisis, perpetuate the false narrative that state-sanctioned marijuana products are medicine, and allow even greater access to dangerous marijuana products. Rescheduling marijuana will only worsen the nation's mental and physical health crisis, leading to increased violence and suffering across the country.

Marijuana is highly addictive.

According to the National Institute on Drug Abuse, up to 30% of users develop some degree of Cannabis Use Disorder, which includes problematic abuse, dependence, and addiction. Yet, there are no specialized cannabis detox facilities. THC is a fat-soluble drug, and it can take months to detox from it. Also, inpatient treatment programs don't accept people with cannabis use disorder because medical insurance doesn't pay for it.

The newest research has concluded that marijuana is EXTREMELY addictive. In fact, according to a meta-analysis of almost 4,000 medical literature abstracts, 47% of regular users will experience symptoms of Cannabis Withdrawal Syndrome (CWS) when they try to quit or when the drug is unavailable.

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But even more than that, marijuana primes the brain for other addictions, and the younger the user is, the worse the damage can be. Individuals who initiate use before the age of 18 are up to 7 times more likely to develop a substance use disorder. As evidence, 54% of people participating in an outpatient treatment program experience CWS, as do 87% of psychiatric units.

State-stationed marijuana is not a safe and effective medicine.

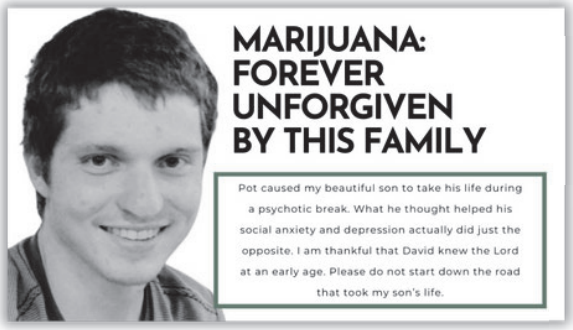
The FDA approves medicine; cannabis-related products that are medicine are Epidiolex and Marinol, which have a standard dosage, formulations, frequency of use, safe delivery systems, and list of potential side effects.

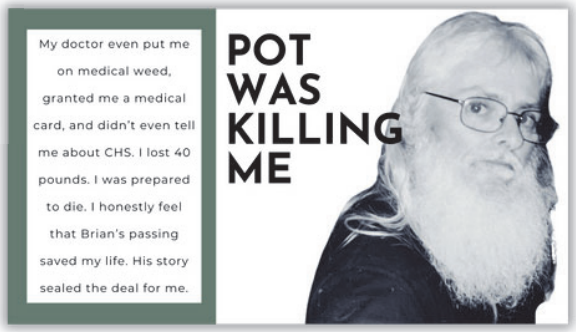
Currently, state marijuana laws supersede the FDA guidelines and permits the marijuana industry to make misleading medical claims and impersonate medical professionals without adequately warning consumers about potential side effects that can severely impact a person's quality of life. The public remains unaware that cannabis can:

- Decrease a person's IQ
- Worsen PTSD symptoms and outcomes
- Deepen depression
- Increase anxiety
- Hinder recovery from substance use disorder
- Increase the risk for head and neck cancers
- Increase the risk for strokes by 42%
- Increase the risk of Autism
- Increase the risk of a heart attack by 25%
- Suppress the Immune System
- Induces seizures
- Increase the risk of Birth Defects and Stillbirth
- Increased risk for Memory loss

Many Americans are losing their health and lives because they think marijuana is medicine. The Every Brain Matters community has published these stories . Please click the images in this document to learn more.

EVERY BRAIN MATTERS





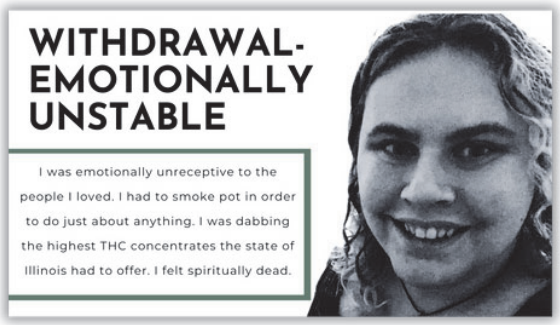
EVERY BRAIN MATTERS

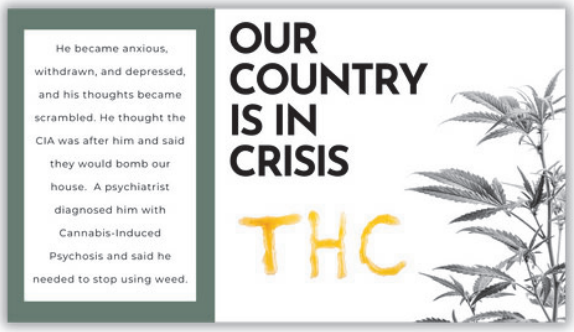
Marijuana is Dangerous

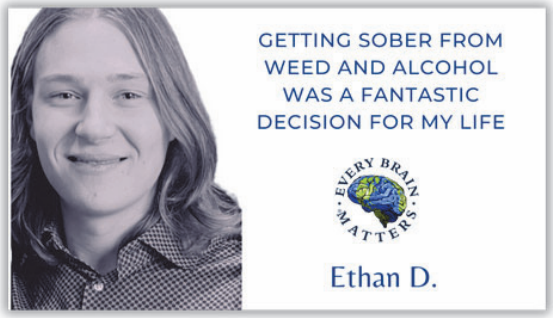
There is a mountain of scientific evidence that clearly shows that marijuana has a host of negative consequences for people of all ages.

Cannabis use can lead to:

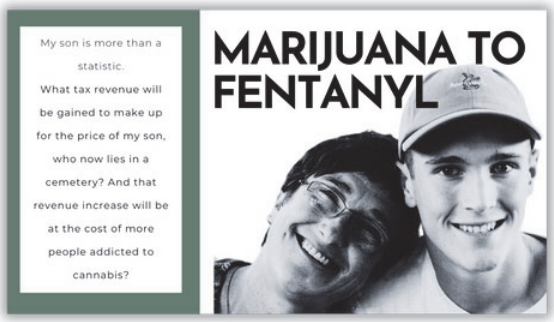
Cannabis Use Disorder or marijuana.

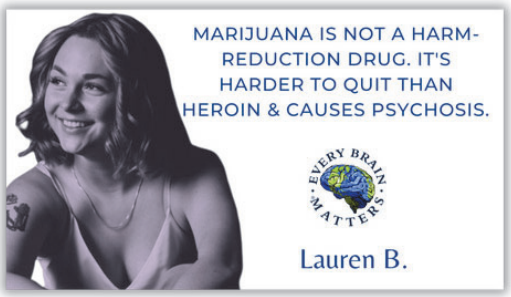


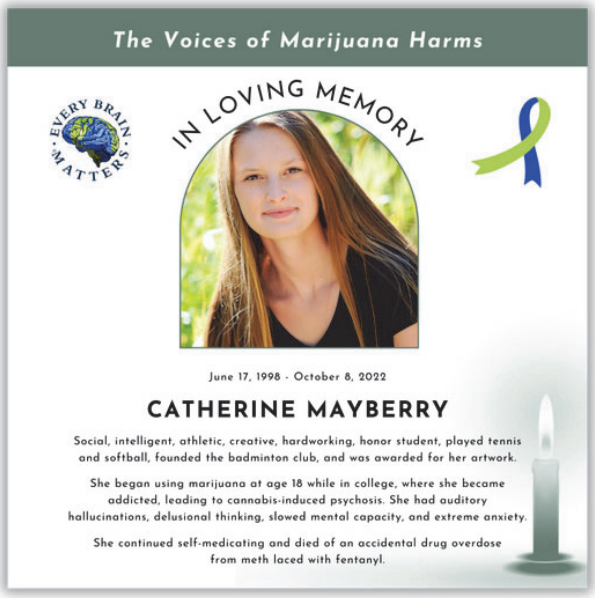




Addiction to more substances, including Fentanyl.



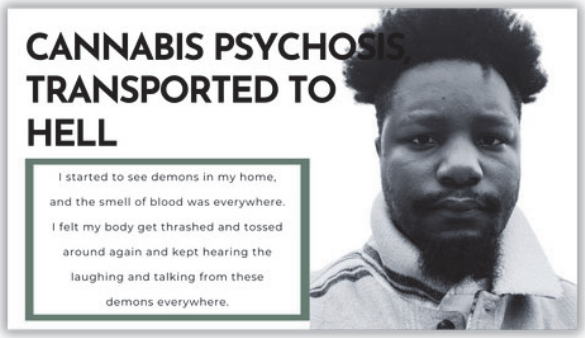


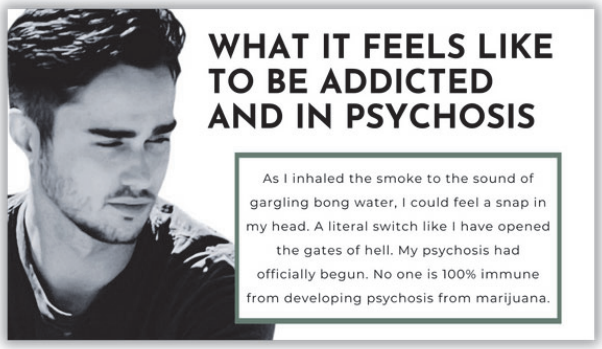


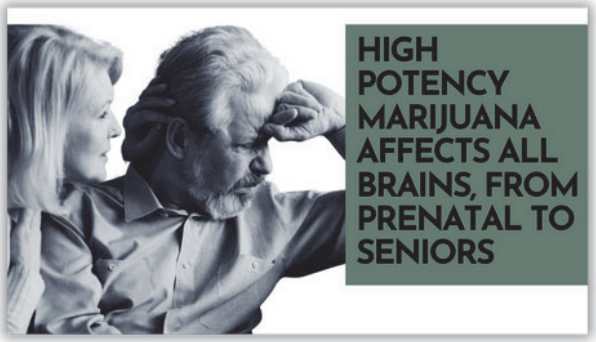
EVERY BRAIN MATTERS

Cannabinoid Hyperemesis Syndrome

Cannabis-Induced Psychosis



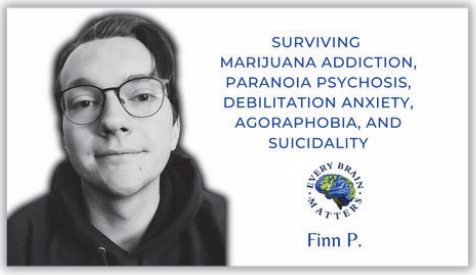


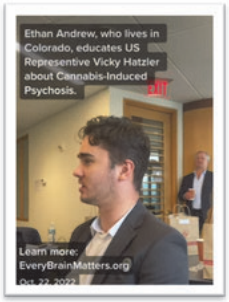


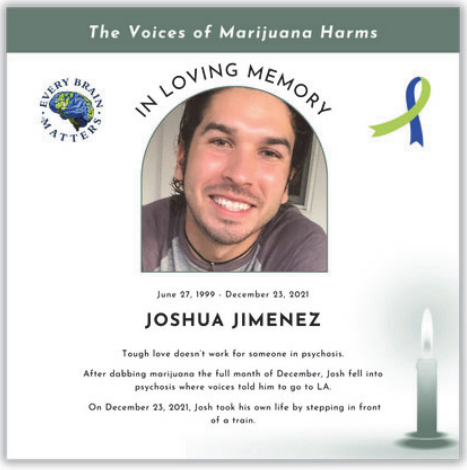
Schizophrenia, especially in young men ages 21-29.

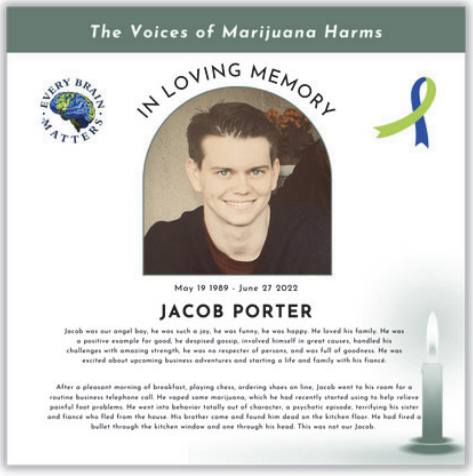
Kyle states that the internet made him believe THC was cool and harmless. He said, "I went from vaping Juuls to vaping THC in a dab pen. My high school bathroom was always filled with kids vaping nicotine and weed. I became addicted and psychotic. It's been a long road for me. I was in psychosis for about two years and have been diagnosed with schizoaffective disorder.

Suicidal Ideation



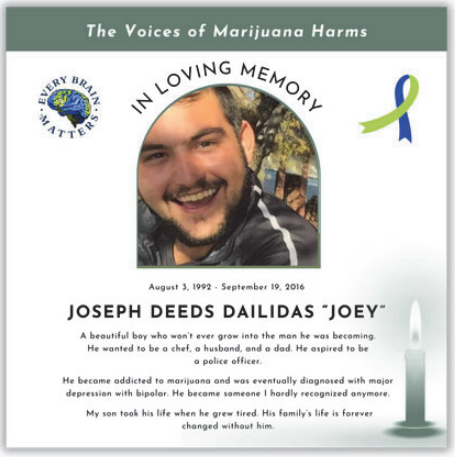


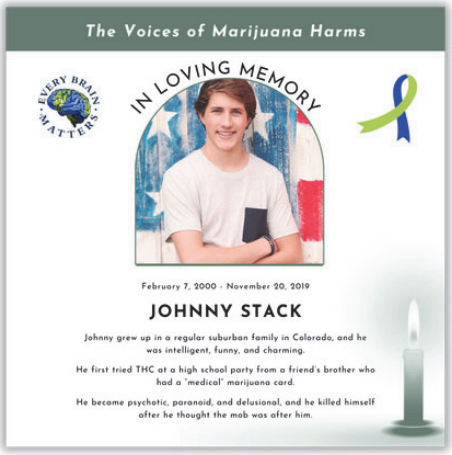


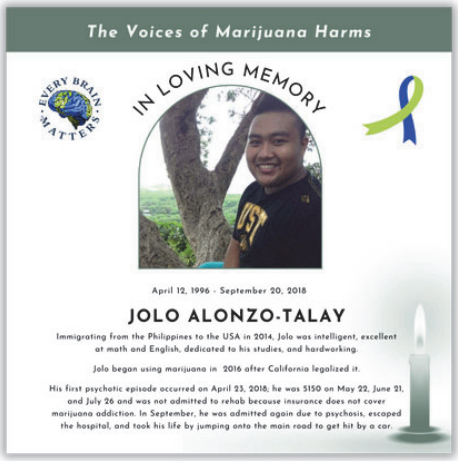


EVERY BRAIN MATTERS

Suicidal Ideation continued



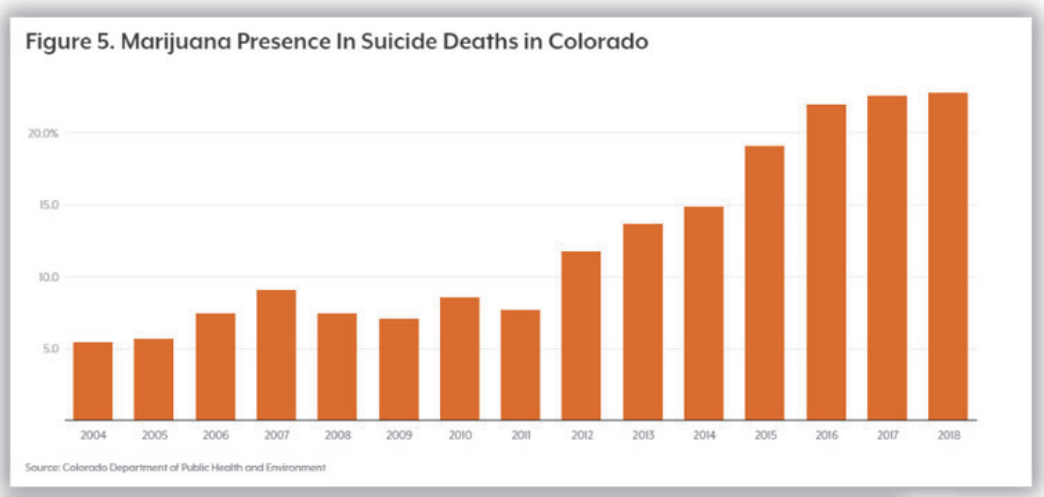


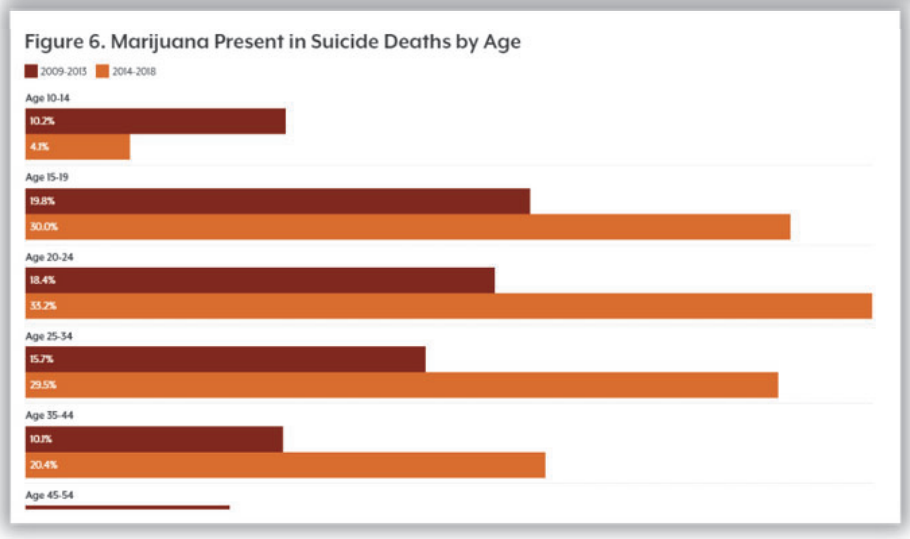


Marijuana is a factor in the increase of suicide deaths in Colorado.

"...Marijuana presence in suicide deaths in Colorado had been rising since 2011 (see Figure 5), over the five years after commercialization, detection of marijuana in suicides increased for all Coloradans except those ages 10-14 compared to the five years prior (see Figure 6). This includes a notable increase among youth ages 15-19, who legally should not have access to marijuana."
~ Colorado Health Institute - Suicide in Colorado - Complex Issues in a Diverse State. May 8, 2023

Source: https://www.coloradohealthinstitute.org/research/suicide-colorado





Most concerning is more evidence showing marijuana use increases the risk of violence.

A 2016 study found that people who smoke pot are seven times more likely to commit violent crimes.

Every Brain Matters is collaborating with Bryn Spejcher, who, despite having no history of mental illness and using only legal marijuana, experienced severe cannabis-induced psychosis. This led her to lose touch with reality, resulting in her stabbing a friend, Chad O'Melia, over 100 times and then stabbing herself more than 40 times. The California Ventura police saved Bryn's life, but Chad did not survive this assault. This tragic case underscores the potential for increased violence linked to cannabis use, and we should anticipate more such violent incidents in the future if the federal government removes cannabis from a Schedule 1 and places it in a Schedule III category.

In an article for Psychology Today, Dr. R. Douglas Fields, Ph.D., wrote, "Continued use of cannabis over the lifetime of the study was the strongest predictor of violent convictions..."

Look at what happened in the first few states after recreational marijuana was legalized:

- Colorado (legalized 2013) – violent crimes are at an all-time high and increased by 61% from 2013 – 2022, when the nation only increased by 3% during that period.
- Washington State (legalized 2013) – After 40 years of below-average crime rates, violent crime has reached record highs, increasing by nearly 20% in just five years.
- California (legalized 2016): Several California cities are suffering a double-digit murder rate. For example, Los Angeles County homicides spiked by 94% between 2019 and 2021.

Rescheduling marijuana is a political move designed to promote its use. The public's understanding of marijuana's effects has been skewed by well-funded campaigns and lobbyists representing Big Cannabis companies. There must be public service announcements warning American's that the THC in the cannabis plant can trigger episodes of psychosis (loss of touch with reality) , and among substances that cause psychosis, THC has the highest conversion rate for temporary psychotic symptoms to chronic psychiatric disorders like schizophrenia and bipolar. This plays a significant role in the rising levels of violence in our country, including mass and school shootings. The focus around marijuana should be on addressing these violent marijuana-related issues, not on rescheduling it.

The Every Brain Matters community has produced a video titled "Marijuana is More Dangerous Than Previously Thought". If the government misleads the public into believing that marijuana is less harmful than previously thought, how will families cope, and how will I secure the funding necessary to continue supporting them? How will I continue to explain that the United State of America picks drugs over the health and safety of American families?

The United States of America is currently grappling with a crisis of addiction, mental illness, and violence. Increasing access to cannabis and allowing more people to profit off the sale of it will only exacerbate this crisis.

Sincerely,

Aubree Adams

Director, Parent, Advocate

CURIO WELLNESS

Docket No. DEA-1362

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Director Milgram,

I am writing to request participation in the upcoming hearing on December 2 regarding the proposed rescheduling of marijuana into Schedule III under the Controlled Substances Act (CSA).

State with particularity the interest of the person in the proceeding
Currently, I serve as the Chairman of the Scientific Advisory Board at Curio Wellness ("Curio" or "The Company"), a multi- state registered cannabis business. Curio's Scientific Advisory Board, which features other renowned research scientists, pharmacologists, and physicians, plays a crucial role in the development of medicinal cannabis products. Curio Wellness was founded and is run by a team of seasoned healthcare executives and technical experts who lead the Company's scientific, product development, manufacturing, and cultivation activities, among others. Since its inception, Curio has prioritized patients through the creation of market-leading wellness products derived from cannabis in traditional dosage forms.

We strongly agree with the findings of the Secretary of the U.S. Department of Health and Human Services ("HHS") in support of the recommendation to reschedule marijuana to schedule III, including the determination that marijuana has a currently accepted medical use ("CAMU").

As the Chairman of the Scientific Advisory Board, I can speak directly to how Curio Wellness utilizes the capabilities of the Scientific Advisory Board, clinical development, and trial-type processes, to develop targeted and patentable wellness products derived from cannabis. Further, as a leader in medicinal cannabis, we can articulate how cannabis listed on the Controlled Substances Act as a schedule 3 drug to schedule III will (i) make it easier to obtain cannabis for use in research, and (ii) eliminate the requirement (that applies to schedule I substances) that FDA review and approve research protocols for cannabis studies.

We at Curio, under my leadership, employ a systematic process that emphasizes data reliability, dosage consistency, medicinal effectiveness, ease of administration, and patient preference. As a result of this comprehensive evaluation process, dosage forms (i.e., pills, capsules, transdermal patches, etc.) are developed for specific disease states and tested with patients on a voluntary basis.

With over 30 years of experience as a pharmaceutical executive and entrepreneur, I have held leadership positions across the pharmaceutical industry, including founder, chairman, and CEO of MiddleBrook Pharmaceuticals, and leadership roles at Shire Laboratories, Merck, and Bristol Myers-Squibb. I have also been named as lead inventor or co-inventor of 58 issued U.S. patents and over 200 associated foreign patents. I have played a leading role in the development of a variety of Food and Drug Administration (FDA) approved medications, including Adderall XR, Carbatrol/Equetro, Claritin, NitroDur, Elocon, and Moxatag. These medications have cumulative sales of over $50 billion.

I serve as an adjunct associate professor for the University of Maryland Department of Pharmaceutical Sciences and an adjunct professor at the University of Rhode Island Department of Pharmaceutical Sciences. I previously served as Vice Chairman of Biotechnology and Chairman of the Technology Council of Maryland. In addition, I have held several advisory positions under the appointment of former Maryland Governors Robert Ehrlich and Martin O'Malley. My academic credentials include a B.S. in Pharmacy, an M.S. in Pharmaceutics, and a Ph.D. in Pharmaceutical Sciences from the University of Rhode Island.

State with particularity the objections or issues concerning which the person desires to be heard
Curio Wellness strongly supports moving marijuana to schedule III under the CSA but is mindful of the inherent conflict between federal and state law that remains, including DEA requirements regarding the handling and dispensing of controlled substances and FDA drug approval requirements. Should the DEA finalize its decision to reclassify marijuana as a schedule III substance, we strongly urge the federal government to ensure that individual states retain autonomy over their respective approaches to cannabis regulation and preserve both state adult-use and medical regulatory programs. Indeed, the federal government can and should work to create certainty and enhance safety for legitimate cannabis businesses, consumers, and patients.

As you know, at least 38 states have passed laws and created administrative infrastructure allowing medical marijuana use, and at least 23 states have legalized the nonmedical use of marijuana by adult users.[1] State regulatory models typically include licensure of cannabis businesses; inspections of cannabis dispensaries and manufacturing facilities; manufacturing

[1] *See* 89 Fed. Reg. at 44,608.

quality requirements; limitations on maximum potency and quantities for purchase by adult users; medical marijuana requirements; registrations or certifications of testing laboratories, transporters, and waste disposal companies; and marijuana product labeling and packaging requirements.

If moved to schedule III, and recognized as having a CAMU, the question of how Federal Food, Drug, and Cosmetic Act ("FD&C Act") requirements for therapeutic products should apply to cannabis almost certainly will come to the fore. If marijuana is moved to schedule III and the federal government continues to exercise enforcement discretion with respect to both the CSA and the FD&C Act, then the cannabis industry will proceed as usual (while enjoying the tax and banking benefits that pertain to schedule III substances). If the federal government, however, decides to begin enforcing the CSA and the FD&C Act against cannabis companies operating under state law, then the cannabis industry will face significant disruption and likely a vast demise.

If the CSA is enforced, then schedule III marijuana could only be dispensed by a licensed pharmacist at a DEA-registered pharmacy.[2] This approach would completely up-end the status quo, where, in many states, (i) medical cannabis patients can be certified and purchase medical cannabis from state-licensed dispensaries, or (ii) adults holding state-issued identification cards can purchase cannabis over-the-counter at a state-licensed dispensary. If the CSA is enforced, then state-licensed dispensaries would no longer be able to dispense cannabis products, significantly disrupting existing state-regulated medical and adult-use programs and forcing the closure of a vast network of small businesses, some of which are minority-owned, resulting in job loss for hundreds of thousands of Americans. Additionally, if the CSA is enforced, then the requirement for a prescription from a licensed practitioner will replace the medical cannabis systems of many states, which allow patients with qualifying medical conditions to obtain a medical cannabis card.

These requirements clearly conflict with state regulatory systems for the licensure of dispensing and manufacturing facilities, and with state regulations on the design and security of licensed facilities.

Further, if marijuana is moved to schedule III, then FDA could begin to enforce the requirements of the FD&C Act against the cannabis industry. Under the FD&C Act, a drug is an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," or an article "intended to affect the structure or any function of the body of man."[3] To determine a product's "intended use," FDA evaluates how the product is promoted in advertising and labeling or in oral statements made by company personnel. FDA also may consider the "design or

[2] *See* 21 U.S.C. § 829(b).
[3] 21 U.S.C. § 321(g)(1).

composition" of the product, as well as circumstantial evidence surrounding its sale, such as sales targets, in determining intended use.[4] Under the FD&C Act, a drug may not be distributed unless an FDA-approved application for the drug is in effect.

FDA will consider a product that contains THC or cannabidiol ("CBD") to be a "drug" based on the THC or CBD content alone because (i) the product's composition suggests that it is intended to treat disease or affect the structure/function of the body, and (ii) FDA has previously approved products containing THC and CBD as drugs.

State briefly the position of the person regarding the objections or issues

Curio Wellness believes that if DEA proceeds with rescheduling marijuana to schedule III, then it should do so without displacing state regulatory regimes for cannabis businesses, adult recreational use, and medical cannabis use. States should be permitted to maintain control of the safe and secure production and distribution of cannabis within their borders under existing state regulatory controls. State regulatory controls are comprehensive, and state officials have proven to be capable cannabis regulators.

Conclusion

I respectfully request the opportunity to be heard at the upcoming hearing to share my perspective on the rescheduling of marijuana. I believe my testimony will contribute meaningfully to the discussion by providing both a scientific and industry-based viewpoint.

Thank you for your consideration. I look forward to your response and the opportunity to contribute to this important discussion.

Sincerely,

Edward Rudnic, Ph.D.
Chief Scientific Officer, Curio Wellness

[4] *See* 21 C.F.R. § 201.128.

9-25-.2024

Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Subject: Docket No. DEA-1362 Request for Hearing

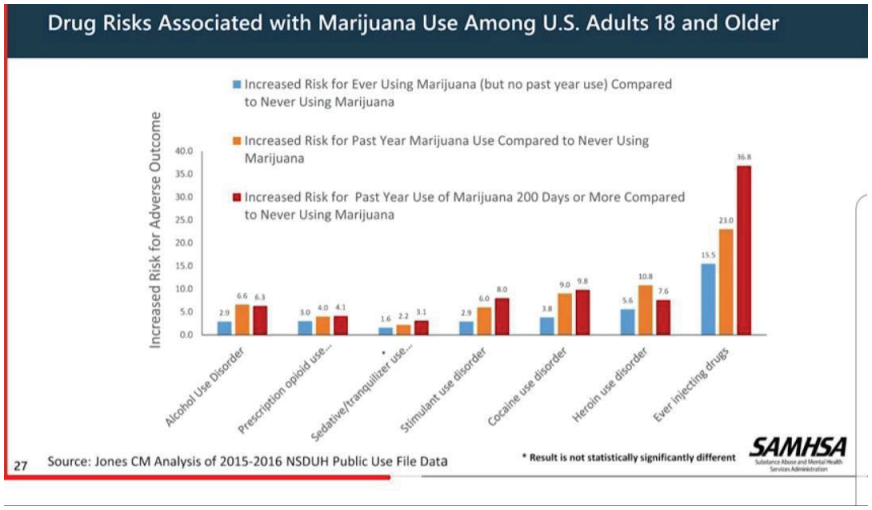
Dear Drug Enforcement Agency,

Thank you for requesting more information from me. I am an aggrieved person in many ways which I will detail below. To summarize: I have personal experience from my youth with cannabis-induced psychosis from low potency marijuana. Secondly, since 2017, I have repeatedly tried to get elected officials in California, the state where I currently live, to educate about the risks of, and to put basic regulations on, marijuana. Because there has been little response from officials, compounded by a powerful industry that squashes any attempt at regulation, we live in a society where few know marijuana can pose any harm at all. At the same time, the increase of marijuana's potency has risen sharply. All of these elements have made a perfect storm, culminating in consequences which are unspeakable. One horrific example from Ventura County, California, is the cannabis-induced psychosis involuntary manslaughter trial of Bryn Spejcher. Because the industry and our elected leaders are not warning the public about the risks, California has increasing problems with drug addiction, mental illness, homelessness and violence. I am aggrieved.

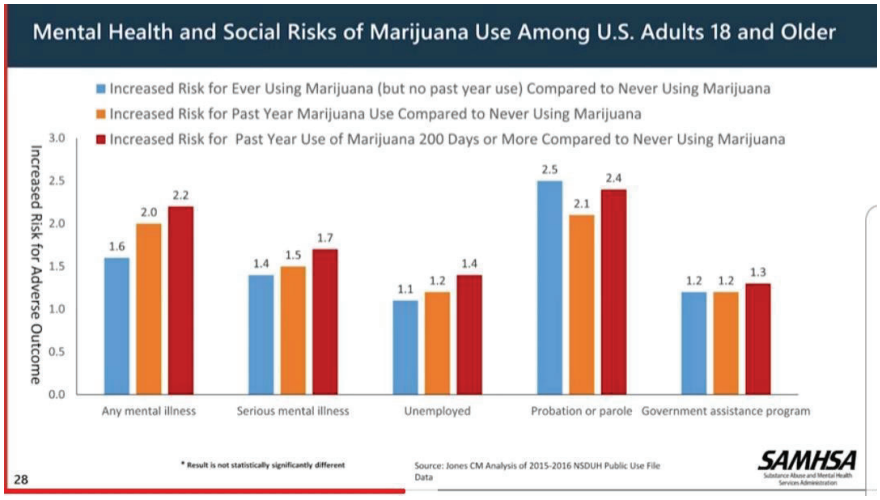
It's said, "As California goes, so goes the nation." For the safety of our country, the Drug Enforcement Agency should keep marijuana in Schedule I. This will give a much-needed clear signal to the nation that marijuana poses serious mental and physical health problems.

YOUTH USE: I am particularly aggrieved because the dearth of public health information about marijuana going back to the 1970's left me and my brother, Kirk, oblivious to the risks. As teenagers, both of us experienced cannabis-induced psychosis on what is considered today to be very low potency weed (1-5% THC). My experience with psychosis happened to one time when I was getting high with my best friend. Suddenly, I didn't know where I was (in the laundry room of my family home) and I didn't recognize my best friend. My friend was fine, but I was not. How a person responds to marijuana, especially in the lower potencies, is determined largely by their genetics. The only way to know if someone has a vulnerability to it is when a negative experience, like paranoia, actually happens.

This loss of touch with reality scared me to death, so I mostly stayed away from the drug. Unlike me, Kirk liked the "fun house" feeling it gave him. He used it every day through high school, college and graduate school. Kirk's experiences were in lockstep with data by the Substance Abuse and Mental Health Services Administration (SAMHSA) showing that marijuana users are more likely to use other drugs, compared to those who never used marijuana.



After graduate school, Kirk was introduced to cocaine and crack and, to the heartbreak of our family, wound up living under a bridge in Seattle. SAMHSA data also shows marijuana users are more likely to experience probation or parole (see attachment).

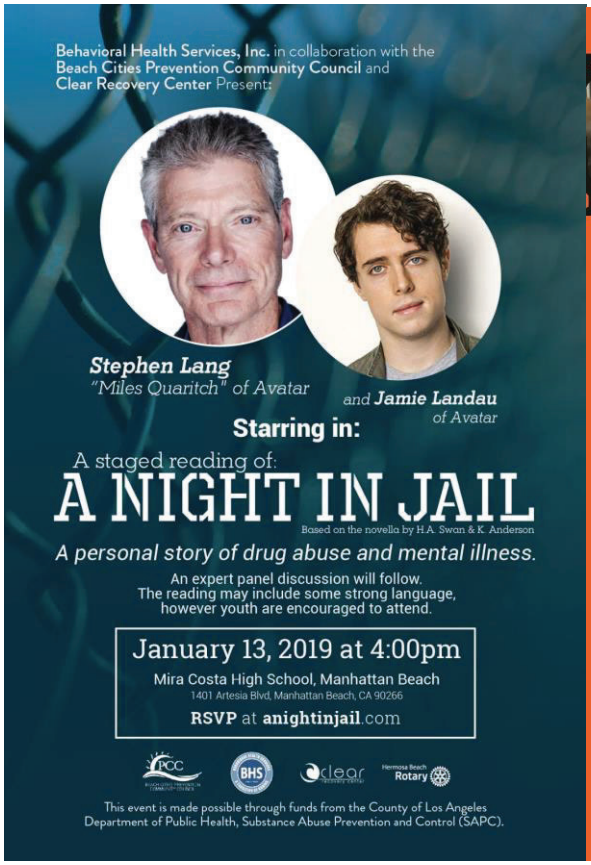


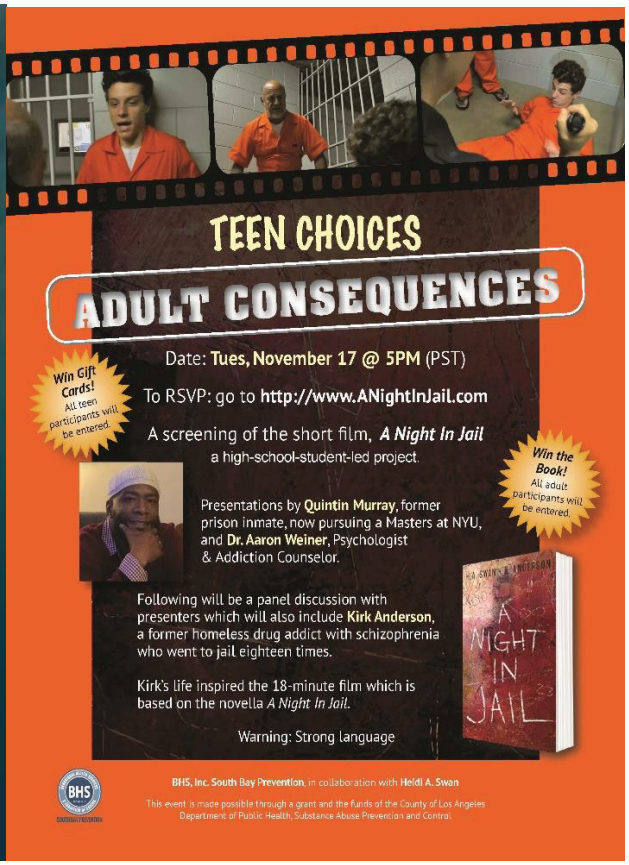
Although Kirk never went to prison, he was booked in the King County Jail 18 times. After many agonizing years, Kirk was diagnosed with schizophrenia. We are thankful to report, Kirk finally got off the streets.

Years later, I saw studies, not dissimilar to a recent National Institutes of Health study, showing marijuana increases the risk to schizophrenia, especially when used by youth. Shocked, I asked Kirk if he knew about this link. He said, “If I knew marijuana would make me crazy I never would have tried it.” I asked Kirk if he would coauthor a story about his life. He agreed.

In 2017, we published a Young Adult novella called A Night In Jail. Inspired by his true life, it’s the first fictional story illustrating the many consequences of using marijuana. We then wrote and produced it as a play and a teen-led short film. We have produced several dramatic presentations with these

works which were followed by expert panels. Because his story illustrates so many of the lifetime risks of using marijuana, we held events that were focused on different outcomes-- like mental illness and incarceration. We had different expert panelists at the various events. See examples below.





One event was focused on homelessness. This event was covered from the local NBC news. The coverage features Kirk.

Frustratingly, my brother's spiral down could have been prevented or at least lessened if the media took research seriously. There was literature in the 1970/80's about the risks of marijuana. Books by Dr. Gabriel Nahas (Keep Off the Grass, 1976) and Peggy Mann's (Pot Safari, 1982) are excellent sources of data which are still relevant today. However, when these books, and other research, came out, the vital information was, and still is, dismissed as *Reefer Madness.* This disdain came at the expense of our youth, like my brother. Indeed, the silence from the media and public health organizations enabled Kirk's life of addiction, leading to his mental illness, time spent in jail, and homelessness.

This not only cost Kirk and our entire family, but it is costing taxpayers today. He has not had a legitimate job in forty years. Between jail, rehab, transitional housing, food stamps, Medi-Cal, Section 8 vouchers, and SSI, he has cost taxpayers an untold sum of money. Kirk is a living example of one of the ways Social Security is being depleted. Every taxpayer should be aggrieved by the massive cost of drug addiction, especially when it afflicts our youth. This is because some drugs can lead to a lifetime of disabling mental illnesses. If serious mental illness of our youth goes up, these same people will not be working jobs. Who will pay into Social Security? If marijuana is rescheduled, we should expect the numbers of people in need of assistance to go up.

FEW ELECTED LEADERS IN CALIFORNIA EDUCATE THE PUBLIC: California has the tragic distinction of being the state where most of our country's homeless population lives. In June of 2019, I flew to Washington D.C. (at my own personal expense) and, along with fellow advocates from www.momsstrong.org (a nonprofit about THC and mental illness/suicide) and led by long-time schizophrenia researcher, Dr.Chrstine Miller, we met with the Drug Advisors to then - Senators Kamala Harris and Dianne Feinstein and others. Months later, I met with the Drug Advisor to then – California Congresswoman Karen Bass. I described to all of them the data showing the link between marijuana and schizophrenia, and that the lack of public knowledge is contributing to California's homelessness. It vexed me that none of our leaders were talking about preventing more people from winding up living on the streets in the first place. We talk about preventing obesity and heart disease—why not addiction and mental illness?

Two months later, in August 2019, our U.S. Surgeon General Dr. Jerome Adams, issued an advisory about the dangers of teen marijuana use, especially with the highly concentrated products. He highlighted the links to psychosis, schizophrenia, depression, anxiety and suicide. I followed up with the drug advisor to Congresswoman Bass about the Surgeon General's warning. There was no reply.

On a very positive note, in October of 2019, two months after the Surgeon General's advisory was released, Dr. Adams testified about the harms of THC at a meeting for the Senate Caucus on International Narcaotics Control held by co-chair Senator Dianne Feinstein. On the recording of the meeting, the advisors we met with in June sat directly behind the senator. My co-advocates and I will never know but, we like to think the meeting we had with Senator Feinstein's advisors may have played a small role in helping this extremely educational meeting to happen.

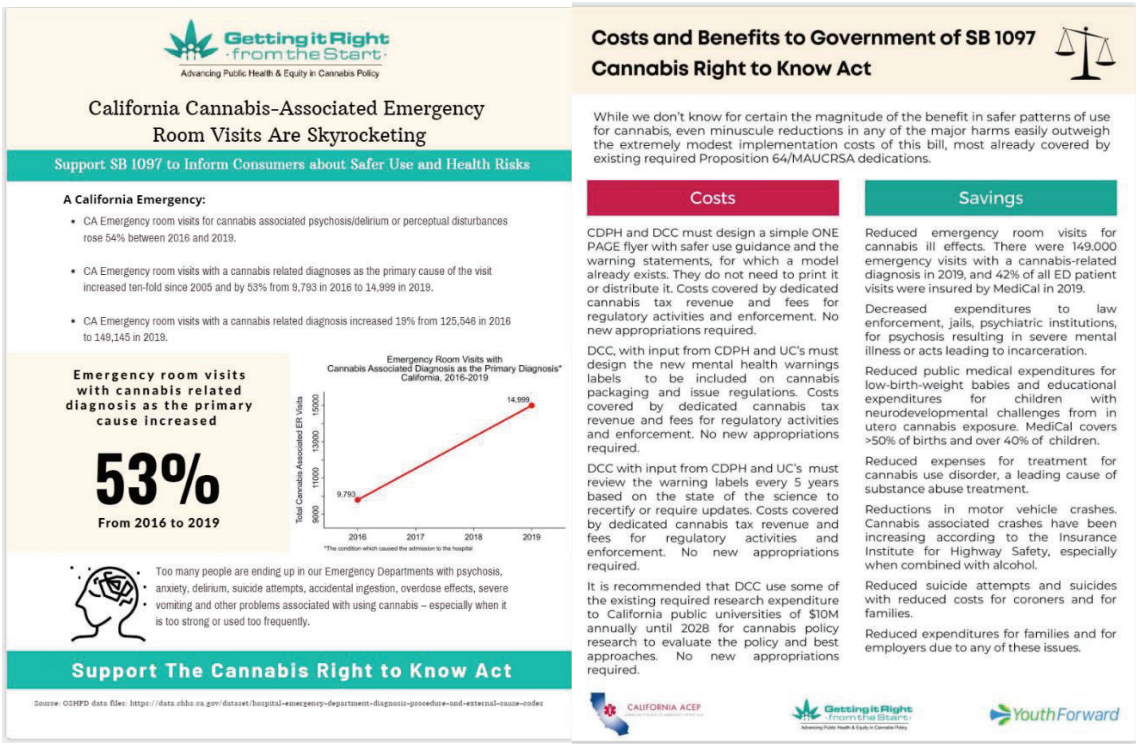
Recently, Mayor Karen Bass has spoken for the first time (that I'm aware of) about preventing homelessness in Los Angeles. However, her approach is to build more housing. There is still silence about preventing two of the afflictions unsheltered people suffer with: drug addiction and mental illness. It's often said that the people who don't have homes must use substances to cope with living on the streets, but the opposite is also true: some people who are living on the streets got there because of their drug use. And some drug use causes mental illness. Why isn't this being discussed? As a resident of Los Angeles, California I am aggrieved.

In 2021, I was working on a project about how legalization in Colorado increased Emergency Room visits due to vomitng and psychosis. During this time, Parents Opposed to Pot referred me to a Fox.com journalist to speak about the ramifications of legalization at the federal level. Some elected leaders insist that the federal government should follow the example of the states that have legalized because, they claim, the states have experienced nothing but success. What about Colorado's rise in ER visits? I am grateful that Fox.com published my comments on video and in print. I said some of our elected leaders are not telling the truth. Inspired by the discrepancy between what some elected leaders say and what data from Colorado shows, I made a short video with a nonprofit that educates about the harms of marijuana, www.everybrainmatters.org (EBM). As a U.S. citizen, and as legalization spreads across our country, I am aggrieved by the fact that the majority of our nation has not learned how public health has been negatively impacted by legalized cannabis in Colorado, one of the first states to legalize.

MARIJUANA INDUSTRY SUCCESSFULLY FOUGHT OFF COMMONSENSE REGULATIONS IN CALIFORNIA: In California's legislative sessions of 2022 and 2023, I volunteered with two bills to put basic public health regulations on marijuana products. The first, SB 1097, was to mandate mental health warnings on high potency THC products. As it is in Colorado, Emergency Room visits due to marijuana exposure have skyrocketed since legalization in California.

Advocates in California were inspired by the legislative success in Colorado to provide mental and physical health warnings with high potency THC products. California has historically been a leader in consumer protections: why wouldn't our state follow what Colorado has done?

I acted as the liaison between Getting it Right from the Start and the victims (family members whose loved ones died by suicide, had mental health problems, were homeless due to their use of marijuana). I would tell everyone when to show up for committee meetings, when to send letters, make phone calls, etc. Their stories were so impactful.



Getting it Right from the Start
Advancing Public Health & Equity in Cannabis Policy

California Cannabis-Associated Emergency Room Visits Are Skyrocketing

Support SB 1097 to Inform Consumers about Safer Use and Health Risks

A California Emergency:

- CA Emergency room visits for cannabis associated psychosis/delirium or perceptual disturbances rose 54% between 2016 and 2019.
- CA Emergency room visits with a cannabis related diagnoses as the primary cause of the visit increased ten-fold since 2005 and by 53% from 9,793 in 2016 to 14,999 in 2019.
- CA Emergency room visits with a cannabis related diagnosis increased 19% from 125,546 in 2016 to 149,145 in 2019.

Emergency room visits with cannabis related diagnosis as the primary cause increased

53%

From 2016 to 2019

Emergency Room Visits with Cannabis Associated Diagnosis as the Primary Diagnosis* California, 2016-2019

*The condition which caused the admission to the hospital

Too many people are ending up in our Emergency Departments with psychosis, anxiety, delirium, suicide attempts, accidental ingestion, overdose effects, severe vomiting and other problems associated with using cannabis – especially when it is too strong or used too frequently.

Support The Cannabis Right to Know Act

Source: OSHPD data files: https://data.chhs.ca.gov/dataset/hospital-emergency-department-diagnosis-procedure-and-external-cause-codes

Costs and Benefits to Government of SB 1097
Cannabis Right to Know Act

While we don't know for certain the magnitude of the benefit in safer patterns of use for cannabis, even minuscule reductions in any of the major harms easily outweigh the extremely modest implementation costs of this bill, most already covered by existing required Proposition 64/MAUCRSA dedications.

Costs

CDPH and DCC must design a simple ONE PAGE flyer with safer use guidance and the warning statements, for which a model already exists. They do not need to print it or distribute it. Costs covered by dedicated cannabis tax revenue and fees for regulatory activities and enforcement. No new appropriations required.

DCC, with input from CDPH and UC's must design the new mental health warnings labels to be included on cannabis packaging and issue regulations. Costs covered by dedicated cannabis tax revenue and fees for regulatory activities and enforcement. No new appropriations required.

DCC with input from CDPH and UC's must review the warning labels every 5 years based on the state of the science to recertify or require updates. Costs covered by dedicated cannabis tax revenue and fees for regulatory activities and enforcement. No new appropriations required.

It is recommended that DCC use some of the existing required research expenditure to California public universities of $10M annually until 2028 for cannabis policy research to evaluate the policy and best approaches. No new appropriations required.

Savings

Reduced emergency room visits for cannabis ill effects. There were 149,000 emergency visits with a cannabis-related diagnosis in 2019, and 42% of all ED patient visits were insured by MediCal in 2019.

Decreased expenditures to law enforcement, jails, psychiatric institutions, for psychosis resulting in severe mental illness or acts leading to incarceration.

Reduced public medical expenditures for low-birth-weight babies and educational expenditures for children with neurodevelopmental challenges from in utero cannabis exposure. MediCal covers >50% of births and over 40% of children.

Reduced expenses for treatment for cannabis use disorder, a leading cause of substance abuse treatment.

Reductions in motor vehicle crashes. Cannabis associated crashes have been increasing according to the Insurance Institute for Highway Safety, especially when combined with alcohol.

Reduced suicide attempts and suicides with reduced costs for coroners and for families.

Reduced expenditures for families and for employers due to any of these issues.

CALIFORNIA ACEP

Getting it Right from the Start

YouthForward

The other bill was to put some kind of regulation on child-attractive products, especially high potency candies that children are mistaking as snacks they would eat.

Cannabis Product or Not?

California, along with the rest of the nation, is experiencing an explosion of children being rushed to emergency departments due to accidental ingestion/overconsumption of psychoactive cannabis products that often mimic some of their favorite brands of candy, soda, or snacks. Don't believe us?

Do you think a child could distinguish these cannabis products from the commonly sold ones or characters they are mimicking?

Legally Sold Cannabis Products

MacFlurry: Flower. Imitates popular fast food chain dessert and it's branding (logo, product colors, graphics), association with ice cream flavoring.

Cocoa Pebbles: Flower. Prominent display of kid friendly imagery, insinuates chocolate flavor, imitates popular cereal marketed to children, use of bright green/orange colors.

Bobbi Hyll: Flower. Depiction of youth friendly imagery, imitates popular animated tv show, it's branding (logo, colors), and characters, use of bright colors & cannabis plant graphic.

Purple Smerf: Flower. Likeness to classic children's cartoon/movie franchise, imitates name, logo and mushroom house imagery. Name of brand, Yogi Baer, is a variant of the name of a popular cartoon character.

Chips: Description of cheese and onion flavors prominently featured, imitates Funyuns and Fritos chips, depiction of famous artist and their popular phrasing style.

Sweet Treats: Packaging and product imitates commonly sold kids rice crispy treat/cereal, features flavor description, contains multiple doses (10/package) not physically separated, use of bright colors.

Gummies: Prominent display of fruits and flavors, including tropical, marketed as having a great taste and being healthy (vegan, gluten free).

Blunts: Flavor description prominently featured, references specific type of chocolate product. **Concentrates:** High potency product, imitates Skittles (Zkittlez), features images of candy and implies "juiciness," use of bright colors.

Beverages: Each can, a normal drink size, has ten doses of cannabis. Arnie's depicts a cartoon character, fruits images and a rocketship, and use bright colors. "Keef Orange Kush" imitates Fanta Orange soda.

Getting it Right from the Start

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The Problem

Due to systemic regulatory failures, California has experienced the proliferation of hundreds of legal cannabis products with characteristics of candies and foods known to attract children and youth. This has led to:

- Annual cannabis exposures reported to California Poison Control increased from below 200 in 2010 to over 1600 by 2020; 50% involved children, half below age 12; There were only 16 total reported gummy exposures between 2010 and 2015 vs. 409 in 2020 alone.[1]
- Cannabis-related emergency department visits in California increased by 75% between 2016 and 2020, mainly involving the consumption of plant material, followed by edibles, concentrates and vaping products, demonstrating that the problem extends beyond just edibles.[2]
- At Rady Children's Hospital in San Diego, children under age 10 testing positive for THC quadrupled since 2016, mostly from edibles, of which three quarters were from candies or gummies. Half led to hospitalization and one in ten to intensive care.[2]
- Widespread vaping epidemic of high THC cannabis products marketed as flavored in CA schools.

1 Roth N, Tam M, Bi C, Kim J, Lewis J, Ali S, Gaskins DE. Changes in California cannabis exposures following recreational legalization and the COVID-19 pandemic. Clin Toxicol (Phila). 2022 May. 60(5):630-636. doi: 10.1080/15563650.2021.2008212. Epub 2021 Dec 5. PMID: 34871109

2 Marijuana Prevention Initiative. (2023). California High Intensity Drug Trafficking Areas Report. Marijuana's Impact on California 2022. Center for Community Research. https://www.norcoconsulting.org/media/attachments/2023/02/01/california-marijuana-impact-report-2022-final.pdf

The Solution: The Cannabis Candy Child Safety Act

AB 1207 (Irwin) will honor the promise and intent of Prop 64 to keep cannabis and its products out of the hands and bodies of our children. The bill will more clearly define and prohibit cannabis products, foods, packaging and marketing that is attractive to children and youth.

The bill is supported by dozens of organizations and individuals representing pediatricians, parents, emergency physicians, public health, youth, and substance use prevention professionals. Key supporters include the California American Academy of Pediatrics, the American College of Emergency Physicians - California Chapter, the Public Health Institute and Youth Forward.

Examples of Canadian products with plain packaging.

Connecticut example of plain packaging

Better is possible: Canada, CT, MA and NJ have already put it place plain packaging practices for cannabis products, AB1207 is far more modest, just curbing some of the most egregious practices in California.

AB 1207: Putting the Health & Wellbeing of California's Children 1st

Child exposure to and consumption of cannabis is neither necessary nor an acceptable by-product of a legal cannabis market. Kids should never get sick because they mistakenly ingested a cannabis product nearly indistinguishable from some of their favorite brands of candy, soda, and snacks. Teens should not be tempted to start use with apple banana joints or vapes. The cannabis industry can flourish without marketing products that are clearly attractive to children.

AB 1207 seeks to make certain minimum changes needed to shape a safer legal cannabis market that does not drive up consumption and protects California's families, children and youth, communities, schools and their future!

Getting it Right from the Start

YouthForward

Support The Cannabis Candy Child Safety Act **#AB1207**

Both bills failed due to pressure from the industry. This leaves the narrative wholly to an addiction-for-profit industry that, like Big Tobacco of yesteryear, is misleading the public. The legislators are sworn to protect the public. I am aggrieved by their dereliction of duty.

See a press release about the failure of SB 1097.

PUBLIC HEALTH INSTITUTE | CALIFORNIA ACEP | YouthForward

PRESS RELEASE

For Immediate Release: August 22, 2022

Press Contact: Zack Kaldveer, Getting it Right from the Start - Public Health Institute, 510-938-2664, zkaldveer@phi.org

Landmark California Cannabis Right to Know Bill Torpedoed by Industry Power

"Cannabis Right to Know Act" Sought to Inform Consumers and Protect Public Health

(CA) Today, sponsors of a landmark California bill (SB 1097 - Pan) to provide the most comprehensive and effective health warnings on cannabis products in the nation were forced to withdraw support just days before an Assembly Floor vote -which would have been a final hurdle before reaching Governor Newsom's desk. SB 1097 (Pan) - The Cannabis Right to Know Act - would have provided consumers with warnings about key, well-recognized health risks associated with cannabis, exacerbated by the market shift to turbocharged, ultra-high THC products.

High-potency cannabis products and frequent use of cannabis have been linked to increased risk of psychosis, dependence, suicide risk and anxiety, can disrupt memory and concentration, and may lead to severe recurrent vomiting (cannabis hyperemesis syndrome). Cannabis use in pregnancy can cause low birth weight and other long term developmental harms for the exposed infant. Cannabis use is also associated with increased motor vehicle crashes. Just today, the National Monitoring the Future Study released its 2021 data showing that use by young adults again hit an all-time high, and that harmful daily or near daily use has nearly doubled in young adults and doubled in older adults since 2011.

In the original bill, these risks would have been prominently displayed using rotating graphic health warning labels on product packaging - an approach implemented successfully in Canada since it legalized cannabis, and on advertising. Unfortunately, aggressive cannabis industry lobbying had already resulted in a significantly watered down, though still valuable version of the bill, that required brochures be made available to consumers and mental health warnings prominently added to product packaging. But industry friendly demands to further dilute the legislation just days before a final Floor vote would have resulted in it bearing little resemblance to its original form, leaving supporters no choice but to pull the bill from consideration.

"Today, even as cannabis use by youth once again hit an all-time high, the cannabis industry's growing influence over legislation succeeded in preventing the public from accessing basic information about the health hazards of cannabis use and simple steps to use it more safely," said **Dr. Lynn Silver, pediatrician and Director of Getting it Right from the Start, at the Public Health Institute**. "Despite unquestionable public support and overwhelming scientific consensus for the bill, industry profits won out over youth's and the public's health."

Buoyed by an energized movement across the state and the leadership of the bill's author and practicing pediatrician, Senator Richard Pan, SB 1097 had passed the State Senate in May and won approval of successive Assembly Committees.

"Turbocharged high THC products like dabs and vapes are increasingly used by young people with no guidance about their serious risks to mental health, the developing brain and other adverse effects," said **Jim Keddy, Executive Director, Youth Forward**. "There is an urgent need for more clear, prominent, accurate and comprehensive health information for our young people to understand these risks - particularly to their brains. Sadly, the cannabis industry made sure that's not going to happen – this year."

Recent research by multiple authors indicates that cannabis health information labels are a proven, effective, and well-accepted approach to educating the public at little or no added cost to government or consumers. SB 1097 was a necessary response to a perfect storm of factors that created an urgent need for the legislation, including:

- Profoundly inadequate current health warnings, with labels typically hidden, disguised, or in extremely small font, and no mention of the risk of mental health problems associated with heavy marijuana use;
- Tripling of daily or near daily use by adults across the state;
- Decreasing public awareness of cannabis's associated health risks;
- Near doubling of use by pregnant women in California from 4.5% to 8%.
- A 53% increase in California emergency department visits for cannabis-related primary diagnoses (149,000 Californians visited EDs with a cannabis related diagnosis in 2019);
- The proliferation of higher and higher potency cannabis products, often flavored, or mimicking candy or other products typically marketed to kids.

"My emergency physician colleagues and I see first hand the growing tide of people ending up in our departments from psychosis, accidental ingestions, car accidents, suicide attempts, and severe vomiting associated with using cannabis," said **Dr. Lori Winston, Emergency Physician and President, California Chapter of the American College of Emergency Physicians.** "As a physician, I'm deeply disappointed that the actions of the cannabis industry mean that Californians won't be provided this bare minimum of accurate and clear information they deserve about health risks and the simple precautions they can take to use more safely."

SB 1097 is supported by a broad statewide coalition that includes the Public Health Institute, Youth Forward, California branches of the American College of Emergency Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, Kaiser Permanente, Los Angeles and Santa Clara counties, county behavioral health directors and health officer associations and over 50 other organizations of youth, parents, health and substance use prevention.

"The legal cannabis industry can thrive without sacrificing the rights of California consumers at the altar of corporate profit," **noted Dr. Silver**. "The movement we've created – and its mission to strike a proper balance between public health and cannabis industry profits – is backed by medical fact and scientific reality. We are on the right side of history, and we will be successful in future legislative efforts."

LACK OF PROTECTIONS AND EDUCATION LEAVE USERS UNAWARE OF HARMS—INCLUDING THE RISK TO PSYCHOSIS AND VIOLENCE: In my new position as an independent contractor for the nonprofit organization, I attended the cannabis-induced psychosis involuntary manslaughter trial of Bryn Spejcher in Ventura County, California. This case illustrates one of the horrifying consequences of not educating the public about the mental health harms of marijuana. Especially when high concentrations are used.

Legalization was rolled out in California in January of 2018. As I've described, there were not any warnings anywhere. And there still aren't. So, back in May of 2018, Bryn Spejcher, a well-educated young Doctor of Audiology from Illinois, was new to California. The way California accepted, and celebrated marijuana was new for a person from her home state, where it had not yet been legalized.

The night the killing occurred, Bryn was visiting with her friend, Chad O'Melia at his home. Chad was a daily user. He considered his use to be "medicinal". If it was Chad's medicine, where were the warnings? Don't all medicines come with a list of precautions and drug interactions? Similarly uneducated, Bryn considered a hit off a marijuana bong to be just another way to be social with a friend. The was no indication anywhere in our state saying otherwise. Bryn had limited experience with use. She never had a negative consequence in all of the 10 times she had used it legally, in legal states. The only feeling she ever got was getting the giggles and the munchies. Chad gave her one hit. She felt nothing. Then Chad said he would make her another hit and he would be sure she felt it. Bryn wasn't interested in another hit, and didn't understand what he meant by that. She thought, if anything, it would only make her laugh more and eat more. She noted the chamber of the bong was thick with smoke. But, it's been said *nobody overdoses on marijuana*, so she didn't think much of it. There's a lot of information about how much alcohol people can safely consume based on age, weight, sex, food intake, etc. But, as I've described, there was no public education on safe intake of marijuana.

Chad prepped and hurriedly put the bong to Bryn's mouth and told her to *take it, take it*. Bryn felt pressured to take it so it wouldn't go to waste. She inhaled. Chad had given Bryn several doses of THC all at one time without describing to her what he had done or what it could do to her. See this televised interview with one of the experts from Bryn's defense describing how Chad *stacked*, or put several doses into the chamber of the bong.

The stacked dosing caused Bryn to become acutely psychotic, she lost touch with her mind and body and became violent. She stabbed Chad over 100 times, killing him. She stabbed her beloved dog. She was plunging the knife into her own throat when the officers arrived. Had they not intervened, she would have also died on the scene (43 cut wounds/stabs into her neck, one just missed her jugular).

At her trial, nearly six years later, Bryn was found guilty of involuntary cannabis-induced psychosis manslaughter. However, the judge sentenced Bryn to probation. He said, in lieu of prison, she would be more beneficial educating the community about the risks of marijuana. Based on my above-mentioned experiences with California's elected leaders and public health organizations, I agree with the judge who determined that Bryn had no way of knowing any of this could happen. But I believe this statement also applies to Chad. He was aware that marijuana could cause psychosis, but he apparently didn't know the psychosis could turn deadly.

Chad's limited understanding was testified to in court. Just weeks prior to his death, Chad gave his roommate several doses of marijuana from the same bong. When his roommate experienced paranoia and hallucinations, Chad thought it was funny. See a YouTube video from 2016 showing an experienced user getting an inexperienced user too high. The inexperienced user's psychosis and vomiting is the joke. It's the entertainment. I am especially aggrieved because, where is the information showing psychosis is dangerous to a brain? That people can die from dehydration from vomiting? Nonprofit YouTube channels like Every Brain Matters don't get nearly the number of views as the YouTube channel, StonersRWeed.

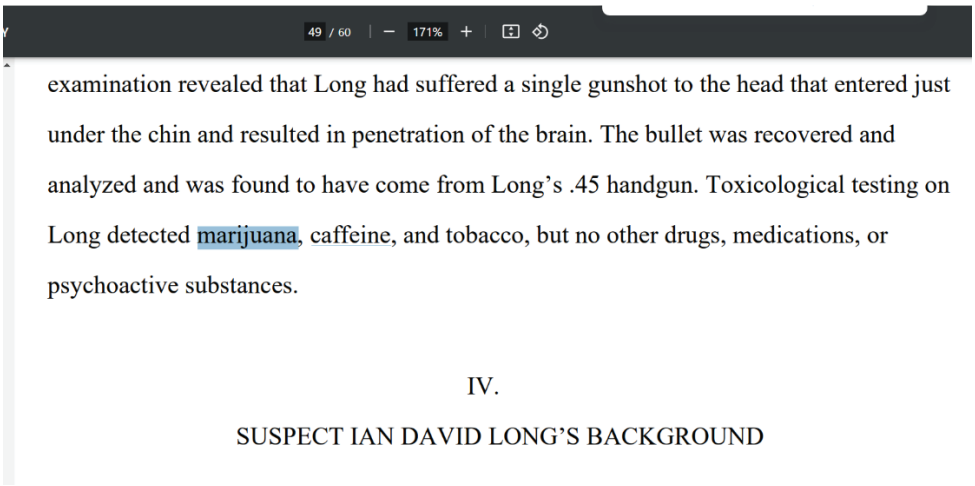
It's clear by the StonersRWeed video that many marijuana users know there are negative mental and physical consequences with using marijuana. It's also clear how they are promoting acceptance and are minimizing marijuana's dire risks. If Chad had any idea this could turn violent, he could have called 911. I am aggrieved by the industry and the California Legislature for how marijuana legalization was rolled out in our state without any protections.

I sat through every day of this very painful trial. I cried for both of the young victims and their families. In some ways, it felt personal to me because when Chad was killed, I had been out with *A Night In Jail* for several months. I was trying to reach people just like Chad and Bryn. In addition to elected leaders, most public health organizations I contacted were not interested in educating about marijuana and mental illness.

Several months ago, I was interviewed again by Fox.com about the Bryn Spejcher trial and the risks of federal legalization. I discussed the failure of the California Legislature to protect its own citizens. See the Fox.com video interview for comments. I was able to describe how the industry promises regulation, but it uses its money and influence to fight every attempt to do so. The industry and our government walk away free, while trials like this take place. In my mind, the obfuscation and misinformation in California is the cause of this true-life horror.

From the beginning of the case, Bryn's lawyers assumed the second (stacked) hit of marijuana Bryn was given was laced with some other substance. It took three years to collect all the evidence to show her acute psychosis was brought on by cannabis only EBM has several Podcasts about Bryn Spejcher's Trial. My co-advocate, Dr. Christy Brown, attended the trial with me. EBM's coverage of Bryn's trial is the only podcast where a viewer can hear from people who actually attended the trial. All other podcasters are extrapolating from what they've seen and read in other media.

One EBM episode on the trial is noteworthy because it has one of Bryn Spejcher's defense attorneys, Robert Schwartz. In that podcast, I comment to Mr. Schwartz that Ventura County, California has had its share of cannabis-induced violence. There's Calvin Sharp who, hallucinating on marijuana, stabbed a young boy to death; Ian David Long, who killed 13 people in a mass shooting: his toxicology report showed that all he had in his system was nicotine, caffeine and marijuana



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And this month, a young adult marijuana user, who, according to his father, was off his meds and using marijuana, and possibly alcohol, hammered his mother to death and then tried to kill his father. It's astounding to me Ventura County isn't warning its own community. If they did, maybe they could prevent more senseless violence, and the rest of California would hear about it, and there would be some education and awareness. Ventura County is home to a lot of pot shops. I am aggrieved by their silence which protects their income from cannabis taxes, but harms public health.

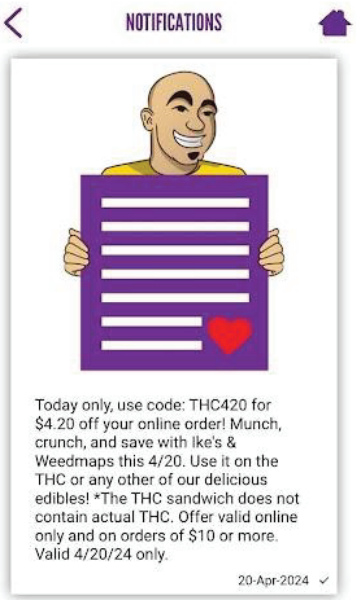
Bryn's sentencing to educate about the harms of marijuana is historic. I do not know of any other time when this has happened. Her probation officers have expressed that they have never done anything like this, either. Bryn must perform 100 hours of education about the harms of marijuana. Every Brain Matters has been approved by Bryn's probation officers to be the exclusive nonprofit to help Bryn educate. For the foreseeable future, I will be working with Bryn and Aubree Adams, the founder of Every Brain Matters, until her hours are complete.

What would happen if marijuana was moved from Schedule I to Schedule III? The general perception would be that marijuana is less dangerous than previously thought and more people will use it. This is especially the case with youth who are shamelessly marketed to by this predatory industry. The look-alike candy products are only one egregious example. If marijuana is rescheduled, our nation will pay dearly. Again, the cost will be mostly on our youth. All of the harm and misinformation I described above will simply get worse. More:

YOUTH USE: I am particularly concerned about the increase in potency and increase of marketing and normalization to youth. I imagine myself as a teenager, with my genetic sensitivity, in today's world: what would happen if someone offered me a child-attractive product that the industry claims are medicine/harmless/funny—while there is little-to-no education to counter their false claims. After taking a puff or eating a gummy, I would surely be someone who would wind up in the Emergency Room. In this 60 second video by California Insider, I describe products of 99% THC potency. And that the dangers of this are not being taught to youth.

In Colorado, an 18 year old with a medical marijuana can purchase hundreds of joints at one time. This is not widely understood. I coproduced a short video with Every Brain Matters about exactly how much can be bought. It's called This Much THC is not Medicinal. Colorado legislation in 2021 cut the amount of concentrates a young adult could buy, but it did not lessen the amount of flower or edibles. It's so surprising. I enlisted Dr. Libby Stuyt an advocate and addiction psychiatrist from Colorado to help with the video. This is one way 18 year olds are getting a ton of product all at one time and re-selling/diverting it to younger kids.

Marijuana is so normalized that businesses wanting to cash in on the "munchies" side effect of weed are directly marketing to kids/young adults on their phones. My college age son, not a drug user, was sent promotions from fast food chains in celebration of 4/20, the unofficial stoners' holiday. There were promotions like: $4.20 for a burger, get $4.20 off an order, etc.



My son and I don't remember restaurants marketing for 4/20 ever before. If we are correct, this indicates there's a new trend and, in this case, it includes magazine and online articles. If marijuana is moved to Schedule III, imagine how much broader this approach will become. Where will a family eat where they can be assured there isn't drug normalization? What other businesses, unrelated to drug use, will find a way to cash in?

ELECTED LEADERS: If marijuana is rescheduled, it will become that much more difficult to convince elected leaders to put commonsense regulations on any of the marijuana products.

Additionally, the downstream impacts of marijuana normalization –increased addiction, mental illness and homelessness-- will be easier to dismiss. It's already become difficult for Americans with mental health problems from marijuana to find treatment. Our country would do well to follow the example of The United Kingdom and open a clinic for cannabis-induced psychosis. Maybe that could help prevent some of the lifelong consequences my brother's life shows. Until that time, will there be enough housing for all the people, like Kirk, who wind up homeless and mentally ill, in part, due to their use of marijuana?

CASES OF VIOLENCE WILL INCREASE: If marijuana is rescheduled, people will have a harder time believing it can cause a person to hallucinate and act out violently. Here are a few examples of marijuana-violence cases since Bryn Spejcher was arrested in 2018: Justin Mohn was a medical marijuana user and decapitated his father. Kolby Parker was smoking pot with his grandfather when he suddenly attacked him with a knife and cut off his ears. Christian Soto smoked pot with his friend, killed him and his mother and then stabbed and ran over a mailman, forced himself into another home and attacked three girls with a baseball bat, killing one. I reached out to the defense and prosecution in the Soto case to tell them that THC can cause psychosis and violence. I described what happened with Bryn Spejcher. Neither side reached back.

Other times, the presence of marijuana in a perpetrator's system gets nothing more than a passing comment. This happened with Ahmad Al Aliwi Alissa, the mass killer of 10 people in a supermarket in Colorado. In the video link, at 4hr 47 min, it is described that Alissa was known to use marijuana when he was in high school. He was 21 at the time of the shooting. Data shows psychosis can occur up to 8 years after use. With Carly Gregg: it was testified she was a user of marijuana vapes. Carly shot and killed her mother and attempted to kill her stepfather. But the attention over her sudden mental health change is

given only to her antidepressants. Of course, all of the substances must be acknowledged. But the mental health dangers of marijuana vapes are not discussed. This silence worsens public understanding.

I hope the information I have provided will help persuade the Drug Enforcement Administration to keep marijuana in Schedule I. In doing so, the DEA will make a strong statement and help put an end to the silence that is harming so many Americans.

Heidi Anderson-Swan

HeidiASwan@yahoo.com

736 Gould Ave #6

Hermosa Beach, California 90254

Respectfully yours,

Heidi Anderson- Swan

VETERANS ACTION COUNCIL

VAC
EST. 2020
ACCESS FOR ALL

UNITED STATES OF AMERICA

25 Sept 2024

Veterans Action Council [VAC] Hereby gives notice that we wish to present and argue our position during the upcoming Hearing by an Administrative Law Judge on cannabis rescheduling:

RE: Schedules of Controlled Substances: Rescheduling of Marijuana

Hearing on the Proposed Rule by the Drug Enforcement Administration

https://www.federalregister.gov/documents/2024/05/21/2024-11137/schedules-of-controlled-substances-rescheduling-of-marijuana

The Veterans Action Council (V.A.C.) is an all-volunteer group of international veterans and venerated professionals in our respective fields.

VAC Written Notice as interested party:

United States military Veterans have suffered tremendous injury from schedule #1 placement of cannabis and while schedule #3 rescheduling will resolve some of these issues Veterans will still continue to suffer unnecessary harm and continued injury under the proposed schedule #3.

Veterans Action Council wishes to be heard on these matters. Schedule 3 is unacceptable given the totality of the evidence and experience we have from the many states' medical cannabis and adult recreational cannabis access programs as well as given the academic and scientific record.

State medicinal access programs and adult recreational access programs operate in a consensus fashion under state laws that more closely aligns with schedule #5 than schedule #3.

The Department of Veterans Affairs - Hospital System, given the fact that schedule 3 will require time consuming FDA approval before such medicines will be able to be dispensed from VA pharmacies, will not be able to integrate cannabis into Veterans pain management or Post Traumatic Stress treatment as they certainly would be able to under a schedule #5 placement or by de-scheduling.

Veterans Affairs hospitals, under schedule 3, will not be able to facilitate cannabis prescriptions until FDA approves new cannabis medicines. Such FDA approvals will be granted for products based upon the many preparations available in dispensaries operated under state laws. This process is onerous and it takes many years for FDA approval for a similar product that is already widely available from said dispensaries.

Schedule #5 placement, or descheduling, will allow the VA doctor to prescribe the medication and for the Veterans Affairs Administration to pay for the product that the Veteran would then go purchase themselves in much the same way that Veterans currently receive a clothing allowance and then buy their own clothes.

Veterans Action Council feels that as a voluntary association of Veterans we are best poised to make this argument on behalf of all United States military Veterans.

Schedule #5 is more appropriate - follow the experience not just the evidence and law: Given the experience in the 30+ states and territories enacting such laws since 1996 and the fact that medical boards, state legislatures, hospital systems, nurses associations, patients, their families, and their communities have carefully thought through the many access issues and have converged on a consensus policy supporting over the counter access that the DEA should instead reschedule to schedule #5 to reflect this reality.

It should be noted that connected to the 30,000 medical care providers and the 6,000,000 patients acknowledged by the FDA, accessing cannabis through a state-authorized medical cannabis recommendation, is a mountain of real-world experience. The FDA is making a conservative opinion based on evidence, but experience is what the FDA lacks; the DEA should be making their recommendation based on experience, law and evidence.

We ask the court to rule that the DEA reschedule cannabis to Schedule #5 or deschedule completely, reflecting its medicinal potential, the overwhelming evidence of its benefits as well as the experience of the millions of patients and their communities. This experience includes state panels dedicated to hearings on a myriad of cannabis subject matters. The conclusion of these many million human-hours in the many states have resulted in what we experience today, a consensus around handling cannabis as an over the counter medication. Veterans Action Council members have participated in dozens of these state processes and can attest to the professionalism of the membership and the seriousness under which they carried out their tasks. These are well thought through experience based recommendations that stand toe to toe with any evidence based evaluation of the FDA.

Background documents & Links:

‘Cannabis’ ontologies I: Conceptual issues with Cannabis and cannabinoids terminology

https://journals.sagepub.com/doi/10.1177/2050324520945797

Cannabis amnesia – Indian hemp parley at the Office International d’Hygiène Publique in 1935

https://www.researchgate.net/publication/360540702_Cannabis_amnesia_-_Indian_hemp_parley_at_the_Office_International_d'Hygiene_Publique_in_1935

VAC Green Paper:

https://www.veteransactioncouncil.com/the-green-paper-1)

Cannabis is an important natural resource:

The critical role of the endogenous cannabinoid system in mouse pup suckling and growth is

exemplified by the fact that without cannabinoids the pups stopped suckling.

https://www.sciencedirect.com/science/article/abs/pii/S0014299901009530

All animals, including vertebrates (mammals, birds, reptiles, and fish) and invertebrates (sea urchins, leeches, mussels, nematodes, and others), have been found to have endocannabinoid systems.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6770351/

The "World Charter for Nature," adopted by the UN General Assembly in 1982, states that:

1. Nature shall be respected, and its essential processes shall not be impaired.

2. The genetic viability on the earth shall not be compromised; the population levels of all life forms, wild and domesticated, must be at least sufficient for their survival, and to this end necessary habitats shall be safeguarded.

https://www.refworld.org/legal/resolution/unga/1982/en/10627

Our council would like to point out that humans have not been alone in this suffering. Cannabis bedding, seed foodstuffs, and medicines denied to animals during this prohibition time period have also caused incalculable harm. Our spirit guide in this work is the beautiful linnet called Cannabina. What we do leaves a lasting impact on our environment and nature. We can and should do better.

Looking ahead, we anticipate that rescheduling or descheduling cannabis will usher in a new era of mutual respect and collaboration. The designation of cannabis as a Schedule 1 substance has placed federal law in an awkward position. Can a law be considered constitutional if it promotes a stance that has long been proven false? This paradoxical situation has surrounded cannabis as a Schedule 1 substance. The federal government has denied its medical use, despite the experiences of over 6 million+ patients spanning generations. As former HHS director Alan Leshner aptly put it, "How can I allocate resources to prove something that I know, as a matter of federal law, is untrue?" Hopefully, we can now reach a consensus on the reality of cannabis and its therapeutic benefits.

VAC Roundtable:

In the Veterans Action Council (VAC) roundtable discussion linked below on rescheduling cannabis, participants shared their final thoughts on the issue as we were joined by Stop the Drug Wars' - David Borden and lawyer Shane Pennington. They highlighted the numerous benefits of cannabis for veterans, including its potential to reduce opioid use and alleviate symptoms of PTSD and chronic pain. While the current petition seeks to reschedule cannabis to Schedule III, the VAC argued that it should be classified as a Schedule V substance or descheduled, reflecting its lower potential for abuse, recognized medical value and experience of state officials and experts and would prefer descheduling outright. The VAC emphasized the

importance of accessible, research-backed cannabis treatment for veterans' health and well-being.

https://youtu.be/_hw7eZZ2qSg?feature=shared

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September 26, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152.
Subject: Docket No. DEA-1362, Request for Participation

Dear Sir or Madam:

Doctors for Drug Policy Reform (the "Organization") and the undersigned, Bryon Adinoff, M.D., hereby requests to participate in the matter of "Schedules of Controlled Substances: Rescheduling of Marijuana" (89 Fed. Reg. 44597).[1]

I. Introduction

Doctors for Drug Policy Reform, or D4DPR (formerly known as Doctors for Cannabis Regulation) supports removing cannabis in all its forms from the Controlled Substances Act. In the context of the proposed rule, however, it is the Organization's position that the medical, scientific, and other evidence supports a Schedule V (alternatively, schedule IV) classification for "marijuana," "marijuana extract," and "naturally derived delta-9-tetrohydrocannabinols" and requests to participate in same in support of its position.

First, the Organization agrees that marijuana has a currently accepted medical use in treatment in the United States and should be removed from Schedule I. As the premier organization of health professionals and scientists specifically organized to provide expert evidence related to the responsible regulation of cannabis, the Organization is best positioned to present additional evidence to support that assessment and to contextualize evidence and argument to the contrary.

Second, while the Organization agrees with HHS that marijuana should be removed from Schedule I, it contends that the evidence, properly considered, supports a classification below Schedule III. Relative to substances in Schedule III and Schedule IV, marijuana has a low potential for abuse and lower psychological/physical dependence.[2] In support of its position, the Organization intends to present fact and expert testimony/opinion from two of its members with relevant expertise, Drs. Bryon Adinoff and David Nathan, and whose CVs/bios are attached. The HHS analysis failed to fully and properly evaluate the relative abuse potential and psychological/physical dependence of marijuana abuse compared to Schedule III, IV, and V drugs, even though the statute requires this analysis and prior scheduling actions involving other drugs

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[1] The Organization previously submitted a request for hearing. For good measure, it also offers this submission.

[2] The Organization notes that "abuse," "dependence," and marijuana are terms in the statute. The use of statutory terms herein indicates no agreement on the propriety of their use in other contexts. For example, "drug abuse" is no longer a diagnosis in DSM-V and therefore, abuse should not be used by medical professionals.

have done it too. At the requested hearing, the Organization intends to provide testimony and evidence on this matter to assist the agency in its final determination.

The Organization also seeks to offer testimony on the issue of the meaning and application of the statutory term "abuse," particularly as it relates to cannabis use. Both FDA and DEA in the past have applied a definition of "drug abuse" as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect."[3] Accordingly, "abuse potential" abuse potential refers to "the likelihood that abuse will occur with a particular drug product or substance with CNS activity."

These definitions, however, are not generally accepted by the medical profession. Rather, drug or substance abuse, as used in the statute, should be understood to capture use or excessive use of a drug in a way that is harmful or detrimental to self, society, or both.[4] This difference is particularly important in assessing the research and epidemiological evidence. A drug like cannabis that is widely available is often used without a prescription but not in a way that is harmful. Indeed, there is currently no way to "prescribe" cannabis, so all cannabis use is used without a prescription.

The Administrative Procedure Act provides "as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function." 5 U.S.C. § 555(b). It similarly provides that the "agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." 5 U.S.C. § 556.

Because the Organization would adversely affected by the proposed rule, has interests that differ from other potential participants, intends to provide non-cumulative evidence to assist the agency's final determination, and is well-suited to cross-examine evidence put forward by industry and rescheduling opponents alike, it requests a rulemaking hearing or to participate in same in support of its position.[5]

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[3] See, for example, https://www.fda.gov/media/116739/download.

[4] The legislative history and agency precedent indicates that a determination that "potential for abuse" should not "be determined on the basis of isolated or occasional nontherapeutic purposes," but rather "there must exist a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community." 76 Fed. Reg. 77330 at 336. Based on this definition, not all cannabis use, whether medicinal or recreational, would constitute abuse.

[5] See *Animal Legal Defense Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 22-23 (D.D.C. 2017) (citing *Nichols v. Bd. of Trustees of Asbestos Workers Local 24 Pension Plan*, 835 F.2d 881, 896-97 (D.C. Cir. 1987)).

II. Interests of the person in the proceeding.

The Organization is a 501(c)(3) non-profit organization that serves as a global voice for licensed health professionals and scientists advocating for evidence-based drug policies and best practices that advance public health, reduce stigma, and minimize harm. Its website is located at https://www.d4dpr.org/.

In 2015, Dr. David Nathan founded the Organization as Doctors for Cannabis Regulation to bridge the gap between the policy of prohibition and the unregulated legalization of cannabis. The Organization has been dedicated to that mission ever since. Since that time, it has served as the premier national physicians' association committed to the responsible regulation of cannabis in the United States and abroad, a global advocate, and represents the voices of over 400 physicians and licensed medical practitioners, in support of evidence-based cannabis regulation and legalization. The Organization is comprised of doctors, nurses, pharmacists—many if not nearly all of whom are registrants.

The Organization is frequently called upon to provide expert testimony in significant legislative and administrative contexts unaffiliated with the cannabis industry. It provided testimony for the first-ever Congressional subcommittee hearing on cannabis legalization and on dozens state-level initiatives and bills pertaining to medical and adult-use cannabis. The Organization frequently collaborates with other advocacy groups to educate the public, including on rescheduling. The Organization is not affiliated with the cannabis industry.

As noted on its website, the Organization also offers curriculums on cannabis education, each of which has been carefully vetted by our D4DPR Board and Experts.

The Organization and its members not only have a particularized interest and are affected by the proposed rule, but are in the best position to provide relevant, material, and not unduly repetitious evidence sought by the agency.[6]

III. Objections or issues concerning which the person desires to be heard.

As an organization of health care professionals and scientists formed years ago to bridge the gap between the policy of prohibition and the unregulated legalization of cannabis, the Organization is generally interested in participating a hearing central to its longstanding mission.

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[6] The Organization and its members are also interested parties considering the differences between Schedule III and Schedule V substances, for example, in dispensing limits for prescriptions. 21 U.S.C. § 829. These differences directly members of the Organization. The Organization further notes that rescheduling (even from I to III) could adversely impact its members because it may affect how medical marijuana is recommended/prescribed or dispensed, which at present, is done based on recommendations and not prescriptions due to its Schedule I status.

The Organization's participation will ensure that the evidence presented by both industry and rescheduling opponents alike are placed in the proper medical and scientific context.

In addition to general participation, as to specific and particularized issues of interest to the Organization, the Organization wishes to be heard on the following two issues.

a. **Physical and psychological dependence *relative* to Schedule III, IV, and V compounds and relative potential for abuse.** The HHS recommendation states that marijuana was compared to controlled substances in schedule III (ketamine) and schedule IV (benzodiazepines, zolpidem, and tramadol), as well as to other schedule II substances (fentanyl and hydrocodone). Without much additional explanation, the recommendation states that it "evaluated the totality of the available data and have concluded that it supports the placement of marijuana in Schedule III." It is unclear, however, whether and how HHS performed a relative potential for abuse and dependence analysis compared to Schedule III and IV substances.

b. **The meaning of "abuse" / "abuse potential" and its application to marijuana.** Historically, FDA and/or DEA has defined "drug abuse" as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect." But this definition or concept is not generally accepted in the medical community, and what constitutes abuse with a culturally available and sanctioned substance cannot be based on whether, on occasion, an individual consumes the substance on their own initiative rather than based on medical advice. Just like few would consider having a glass of wine with dinner to be alcohol abuse, few medical professionals would seriously consider smoking marijuana once a week on Friday to relax after work to be "abuse." The definition of "abuse" and "abuse potential" is important because it undergirds the HHS findings with respect to marijuana's "potential for abuse." Properly considered, marijuana does not have a "potential for abuse" any greater than drugs in the benzodiazepine class (Schedule IV).

IV. Brief Statement on the Issues.

a. **Physical and psychological dependence *relative* to Schedule III, IV, and V compounds and relative potential for abuse.** The HHS recommendation does not appear to do a meaningful comparative analysis in assessing scheduling factor three, even though the statute demands that in determining a final scheduling placement among Schedules III, IV, or V, the agency must compare physical and psychological dependence among them.[7] Notably, both agencies have done this analysis in the past.

[7] For example, Schedule III, factor 3 (21 U.S.C. § 812(b)(3)(C)) is "Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence," while Schedule IV, factor 4 (21 U.S.C. § 812(b)(4)(C)) is "Abuse of the drug or other

For example, the agency concluded in 2013 that Lorcaserin should be placed in Schedule IV (78 Fed. Reg. 26701), based on an abuse potential study comparing lorcaserin to zolpidem (Schedule IV) and ketamine (Schedule III). The agency concluded in 2005 that pregabalin warranted Schedule V placement because "withdrawal effects of pregabalin are less severe than with other substances currently controlled in Schedule IV." (70 Fed. Reg. 43633.)

The HHS analysis on relative abuse potential, reproduced below, is hard to understand:

> *[T]he rank order of these substances regarding harms does not consistently align with the relative scheduling placement of these drugs in the CSA due to the pharmacological differences between various classes of drugs.*
>
> *There are a number of confounding factors that likely influence the adverse outcomes measured in various epidemiological databases and account for the rank ordering of the drugs evaluated on these measures. For example, each substance has associated with it a different population that abuse that substance, a different prevalence of abuse, and a different profile of severe adverse outcomes in a setting of nonmedical use and abuse. Thus, it is challenging to reconcile the ranking of relative harms associated with the comparators used in this evaluation when the rankings differ across various epidemiological databases, and when these rankings often do not align with the scheduling placement of these comparators under the CSA.* ***To address these challenges, we evaluated the totality of the available data and have concluded that it supports the placement of marijuana in Schedule III.***

The Organization does not believe this analysis is sufficient, and it intends to provide detailed testimony from two witnesses on the low physical and psychological dependence of cannabis relative to Schedule III and IV substances.[8] In particular, the analysis does not properly compare cannabis to the benzodiazepine class in Schedule IV, and it is well documented that benzodiazepine abuse results in significant physiological and psychological dependence. The proposed rule similarly recognizes that the public health risk of benzodiazepines is substantially greater than the risk presented by cannabis. The evidence will show that compared to benzodiazepines, abuse of marijuana leads to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

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substance may lead to limited physical dependence or psychological dependence *relative to the drugs or other substances in schedule III*." To determine whether a drug properly is placed in Schedule III or IV, it is therefore necessary to consider the relative dependence of the substance compared to other substances in Schedule III. The same can be said of Schedules IV and V.

[8] One witness has recognized expertise in addiction and substance use disorders. The other has expertise in cannabis policy and psychiatry.

b. **The meaning of "abuse" / "abuse potential" and its application to marijuana.** Marijuana, like most drugs, can be "abused." But what constitutes "abuse" in the context of a culturally available and state-regulated substance cannot be based simply on whether, on occasion, an individual consumes the substance on their own initiative rather than based on medical advice, without any harm to the individual. Few would consider a glass of wine with dinner to be alcohol "abuse." Likewise, occasional marijuana consumption that presents no individual or societal harm is not "abuse." The proposed rule recognizes that "the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others." None of that is "abuse," and in assessing prevalence as part of a potential for abuse assessment, DEA should neither include medical uses of marijuana nor non-problematic non-medical uses.

All notices to be sent pursuant to the proceeding should be addressed to:

Bryon Adinoff
812 S Gaylord St
Denver, CO 80209

David L. Nathan, MD, DFAPA
Princeton Psychiatry & Consulting, LLC
601 Ewing Street, Suite C-10
Princeton, NJ 08540

and

Matthew C. Zorn
Yetter Coleman LLP
811 Main Street, Ste. 4100
Houston, TX 77002

Respectfully yours,

Bryon Adinoff, M.D.
President, Doctors for Drug Policy Reform

CURRICULUM VITAE

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Website: www.adinoffaddictionpsychiatry.com
https://som.ucdenver.edu/Profiles/Faculty/Profile/27480

Twitter: @BryonAdinoff
@editor_AJDAA

Education:

1983-1986	Medical Staff Fellow, Laboratory of Clinical Studies, Division of Intramural Clinical and Biological Research, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD
1979-1983	Psychiatry Residency, Tulane University Affiliated Hospitals, New Orleans, LA
1975-1979	M.D. – College of Human Medicine, Michigan State University, East Lansing, Michigan
1971-1974	B.G.S. - University of Michigan, Ann Arbor, Michigan

Faculty Appointments:

2019-	Clinical Professor, Department of Psychiatry, University of Colorado Anschutz Medical Center
2017-2019	Adjoint Professor, Department of Psychiatry, University of Colorado Anschutz Medical Center
2009-2018	Graduate Faculty, Rehabilitation Counseling Psychology Program, UT Southwestern Medical Center
2006-2018	Tenure, Department of Psychiatry, UT Southwestern Medical Center
2005-2018	Adjunct Professor of Brain Imaging Research, School of Behavioral and Brain Sciences, University of Texas at Dallas
2000-2018	Member, Clinical Psychology Graduate Program, UT Southwestern Graduate School of Biomedical Sciences
1998-2018	Professor, Department of Psychiatry, UT Southwestern Medical Center
1998-2018	Clinical Associate Professor, Department of Family Practice, University of North Texas Health Science Center at Fort Worth
1995-2018	Distinguished Professor in Alcohol and Drug Abuse Research, Department of Psychiatry, University of Texas Southwestern Medical Center at Dallas
1995-1998	Associate Professor, Department of Psychiatry, UT Southwestern Medical Center
1992-1995	Associate Professor, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston, SC
1988-1992	Assistant Professor, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston, SC
1985-1988	Adjunct Assistant Professor, Department of Psychiatry, George Washington University, Washington, DC

Hospital Appointments:

2014-2018	Attending Staff, UT Southwestern Medical Center, Dallas, TX

1997-2018	Attending Staff, Parkland Medical Center, Dallas, TX
1995-2018	Attending Staff, VA Medical Center, Dallas, TX
1994-1995	Attending Staff, Medical University of South Carolina, Charleston, SC
1988-1995	Attending Staff, VA Medical Center, Charleston, SC
1986-1988	Senior Staff Fellow, Laboratory of Clinical Studies, DICBR, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD
1983-1986	Ward Administrator, Alcohol Unit, Clinical Center, National Institute of Health, Bethesda, MD
1982-1983	Part-time Staff, East Louisiana State Hospital, Jackson, LA
1982-1983	Part-time Staff, New Orleans Adolescent Hospital, New Orleans, LA
1981-1983	Part-time Staff, Charity Hospital, New Orleans, LA
1980-1983	Part-time Staff, Veterans Administration Hospital, New Orleans, LA

Administrative Appointments:

2013-2018	Director of Research, Mental Health, VA North Texas Health Care System
2005-2018	Chief, Division on Addictions, University of Texas Southwestern Medical Center at Dallas
1995-2005	Director, Clinical Center for Addictive Diseases, University of Texas Southwestern Medical Center at Dallas
1997-2005	Medical Director, Substance Abuse Team, Mental Health, VA North Texas Health Care System, Dallas
1996-1997	Member, Transition for Mental Health, VA Medical Center Dallas, TX
1995-1997	Chair, Substance Abuse Subcouncil for VISN #17 Mental Health Advisory Council
1995-1997	Director, Chemical Addiction Program, VA Medical Center, Dallas, TX
1992-1995	Director, Substance Abuse Treatment Center, VA Medical Center, Charleston, SC
1988-1992	Medical Director, Substance Abuse Treatment Center, VA Medical Center, Charleston, SC
1986-1988	Chief, Unit of Outpatient Studies, Laboratory of Clinical Studies, DICBR, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD
1986	Acting Chief, Section of Clinical Science, Laboratory of Clinical Studies, DICBR, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD

Other Positions:

1975	Research Assistant, Ed Domino, M.D., Department of Pharmacology, Lafayette Clinic, Detroit, MI
1973-1974	Counselor, Drug Help, Ann Arbor, MI
1972-1973	Research Assistant, James Woods, Ph.D., Department of Pharmacology, University of Michigan, Ann Arbor, MI

Board Certification:

2014	Addiction Psychiatry, Recertified
Dec. 31, 2003	Addiction Psychiatry, Recertified
March, 1993	Addiction Psychiatry #013
November, 1985	American Board of Psychiatry and Neurology #27234
1979	FLEX

Licensure

2015-	Colorado (#DR.0055904)
1996 - 2018	Texas (#J9942)
1989 - 1995	South Carolina (#14229)

1985 - 1988	Washington, DC (#15002)
1983 - 1988	Maryland (#D30259)
1979 - 1983	Louisiana (AA-93-82627)

Professional Societies
American College of Neuropsychopharmacology, Fellow
American Psychiatric Association, Distinguished Life Fellow
American Association of Addiction Psychiatry, Founding Member, Distinguished Fellow
Doctors for Cannabis Regulation, Founding Member, President

Administrative

2022-	President, International Society of Addiction Journal Editors (ISAJE)
2020-2022	Vice-President, International Society of Addiction Journal Editors (ISAJE)
2018-	Member, Legislative Committee, Colorado Psychiatric Society
2018	Member, Diversion Prevention and Awareness Task Force, Parkland Memorial Hospital
2018-	Board of Directors, International Society of Addiction Journal Editors (ISAJE)
2015-2017	Ethics Committee, American College on Neuropsychopharmacology
2015-2018	Co-chair, New Investigators Award Committee, VA North Texas Health Care System
2015-2017	Member (Alternate), Research and Development Committee, VA North Texas Health Care System
2014-2018	Chair, Committee on Practitioner Peer Review Assistance (COPPRA), Combined Parkland Memorial Hospital – UT Southwestern Medical Center
2014-2017	Member, Opioid Safety Initiative, VISN17, Veterans Hospital Administration
2013-2018	Chair, Mental Health Research Committee, VA North Texas Health Care System
2012-2013	Member, Chair's Subcommittee on the Advising System, Department of Psychiatry, UTSW
2012-2017	Chair, Substance Use Disorder Leadership Council, VISN17, Veterans Hospital Administration
2010-2018	Co-director, Region VIII, American Academy of Addiction Psychiatry
2012	Member, Program Committee, Research Society on Alcoholism
2010-2014	Vice-chair, Committee on Practitioner Peer Review Assistance (COPPRA), Combined Parkland Memorial Hospital – UT Southwestern Medical Center
2011-2013	Coordinator for UT Southwestern Medical Center, Metroplex Day
2010-2017	Treasurer, Executive Board, Texas Research Society on Alcoholism
2010-2011	Member, Psychiatric Research Education Program Mentor Committee, Department of Psychiatry, UT Southwestern
2008-2011	Member, Human Research Committee, American College on Neuropsychopharmacology
2007-2009	Chair, Research Development Committee, NIDA Clinical Trials Network
2006-2018	Member, Accreditation and Promotion Committee, Department of Psychiatry, UT Southwestern
2006-2016	Member, Executive Committee, Department of Psychiatry, UT Southwestern
2005-2007	Member, Research Development Committee, NIDA Clinical Trials Network
2002-2004	Member, Public Policy Section, American Association of Addiction Psychiatry
2001-2018	Chair, Clinician's Promotion Board, Mental Health Service, VA North Texas Health Care System
1998-2001	Member, Task Force on Addictive Disorders, Texas Society of Psychiatric Physicians

1999-2011	Member, Committee on Practitioner Peer Review and Rehabilitation (COPPRA), Combined Parkland Memorial Hospital – UT Southwestern Medical Center
1997-2018	Chair, Addiction Council, VA North Texas Health Care System
1997-2000	Member, Continuity of Care Committee, VA North Texas Health System
1994	Member, Substance Abuse Program Guide Task Force, VA Central Office
1994-1995	Member, Institutional Review Board for Human Research, Medical University of South Carolina, Charleston, SC
1994-1995	Member, Pharmacy and Therapeutics Committee, VA Medical Center, Charleston, SC
1992-1995	Medical Review Officer, VA Medical Center Charleston, SC
1991-1993	Chairman, Medical Record Review Committee, VA Medical Center, Charleston, SC
1991-1995	Member, Substance Abuse Executive Committee, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina
1990-1993	Member, Strategic Planning Committee, VA Medical Center, Charleston, SC
1989-1993	Member, Drug Utilization Review Committee, VA Medical Center, Charleston, SC
1989-1994	Alternate Member, Institutional Review Board for Human Research, Medical University of South Carolina
1989-1991	Member, Medical Record Review Committee, Charleston VA Medical Center
1986-1988	Chairman, Institute Clinical Research Subpanel, Laboratory of Clinical Studies, DICBR, National Institute on Alcohol and Alcoholism
1986-1988	Member, Human Research Review Panel, Clinical Center, National Institutes of Health
1986-1988	Member, Quality Assurance Coordinators, Clinical Care, National Institutes of Health

Grant Reviews

Reviewer, Grant Award Opportunity, Institute of Cannabis Research (ICR), Colorado State University Pueblo, 2021
Member, Scientific Advisory Committee, Medical Marijuana Research Grant Program, Colorado Department of Public Health and Environment, 2018
Member, “Center of Excellence” Grant Program (P-50), (ZDA1 NXR-B), NIDA (2015)
Member, Special Emphasis Panel/Scientific Review Group for Specialized Alcohol Research Centers, (ZAA1 P50), NIAAA (2013)
Chair, Comprehensive Research Center Review (GG-57 P60), NIAAA (2013)
Member, Center Review (GG-58 P50), NIAAA (2013)
Ad-hoc reviewer (ZRG1) EMNR (2012)
Temporary Member, (ZRG1), NIDA (2011)
Chair, I/Start Special Emphasis Panel (ZDA1), NIDA (2009, 2010, 2012, 2013, 2014, 2015)
Temporary Member, Neurobiology A Integrated Review Group, Office of Research and Development, Department of Veterans Affairs (2010)
Chair, Neurobiology/Therapy Alcohol and Drug Abuse Panel (PR093916), Peer Reviewed Medical Research Program (PRMRP), US Army Medical Research and Materiel Command, Department of Defense (2009)
Temporary Member, Neurobiology 2 Integrated Review Group, Office of Research and Development, Department of Veterans Affairs (2009)
Member, I/Start Review (ZDA1), NIDA (2008)
Member, Special Emphasis Panel (ZAA1), Center for Scientific Review, NIAAA (2007)
Member, Research Center Review Committee, Department of Veterans Affairs (2006)
Chair, Special Emphasis Panel, Biochemical Research Review Subcommittee (ZAA1 CC), Center for Scientific Review, NIAAA (2005)
Member, Clinical and Treatment Subcommittee (AA3), Center for Scientific Review, NIAAA (2004-2008)
Consultant, Training and Career Development Subcommittee, NIDA (2002)
Member, Site Review, National Center for Research Resources, NIH (2000)

Member, NIDA Special Emphasis Panel, Medication Development Panel (1999)
Member, Site Review, Alcohol Research Center, NIAAA (1998)
Member, Research Advisory Group, Department of Veteran Affairs (1993-1995)
Consultant, Fellowship Programs in Substance Abuse Treatment, Department of Veteran Affairs (1994)

Editorial Activities
2012- Editor-in-Chief, The American Journal of Drug and Alcohol Abuse
2007-2011 Editorial Board, The American Journal of Drug and Alcohol Abuse

Journal Reviews
Editorial Advisory Board, Sci-Mat
Advisor, Handbook of Psychiatric Measures and Outcomes, APA
Tenth Special Report to the U.S. Congress on Alcohol and Health, NIAAA Addiction
Consultant, WHO, Guidelines for Psychosocially Assisted Pharmacotherapy of Opioid Dependence
Guest Field Editor, International Journal on Neuropsychopharmacology
Alcohol and Alcoholism
Alcoholism: Clinical and Experimental Therapeutics
Alcohol Health & Research World
American Journal of Psychiatry
American Journal of Addictions
American Journal of Cardiology
Archives of General Psychiatry
Biological Psychiatry
CNS Drugs
Drug and Alcohol Dependence
Drugs, Habits, and Social Policy
Harvard Review of Psychiatry
Hormones and Behavior
JAMA
JAMA Network Open
Journal of Clinical Psychiatry
Journal of Clinical Psychopharmacology
The Journal of Critical Illness
Journal of Substance Abuse Treatment
Medical Toxicology
NeuroImage
Neuropsychopharmacology
Pharmacology, Biochemistry, and Behavior
Psychiatry Research
Psychoneuroendocrinology
Psychopharmacology

Grants
2017-2018 Consultant, National Institute on Alcohol Abuse and Alcoholism. R43. Aware (A wearable awareness with real-time exposure): Rapid Wearable Alcohol Diagnostics. $250,000. (PI: Sriram Muthukumar)
2013-2016 Principal Investigator, National Institute on Drug Abuse. R21. “Lidocaine infusion as a treatment for cocaine relapse and craving.” $275,000.
2012-2015 Co-Investigator, National Institute on Drug Abuse. K08. “Cardiovascular risks of prescription amphetamine use in a national veterans study.” $450,000 (PI: Arthur

Westover)

2012-2014 Principal Investigator, National Institute of Arthritis and Muskoloskeletal and Skin Diseases (NIAMS). R21. “Striatal dopamine release in response to ultraviolet light in compulsive tanner.” $230,000.

2013-2017 Co-investigator, National Institute on Drug Abuse. R01. Genetic and environmental modulators of the brain’s response to marijuana cues. $1,865,000 (PI: Francesca Filbey).

2011-2012 Co-investigator, University of North Texas. “Exercise intervention for psychoneuroendocrine comorbidities and relapse prevention in women recovering from substance abuse.” (PI: Vingren)

2012-2013 Co-investigator, National Institute on Drug Abuse. R03. “Independent Component Analysis Based Support Vector Machine Classification Method: Application to functional MRI data from cocaine-addicted patients.” $100,000 (PI: Mutlu Mete)

2012-2014 Co-Investigator, American Heart Association, “Cardiovascular Risks of Prescription Amphetamine Use in Adults”. $70,000 (PI: Arthur Westover)

2010-2012 Co-investigator, National Institute on Drug Abuse, U10 “Clinical Trials Network: Texas Node.” $1,000,000

2009-2012 Co-investigator, Department of Veteran Affairs, Merit Review. “Extinction of Fear Memories with Glucocorticoids in Veterans with PTSD.” $745,550 (PI: Alina Suris)

2007-2012 Principal Investigator, National Institute on Drug Abuse, R01 “Impulsivity, Neural Deficits, and Cocaine Relapse.” $1,000,000.

2007-2012 Principal Investigator, Integrative Neuroscience Initiative on Alcoholism–East, National Institute on Alcohol Abuse and Alcoholism. U01 “Stress, HPA Axis Dysfunction, and Relapse in Alcoholism.” $1,150,000

2006-2010 Principal Investigator, Department of Veteran Affairs, Merit Review. “Trauma, Stress, and Persistence of HPA Axis Dysregulation in Alcoholism,” $600,000

2005-2010 Principal Investigator, National Institute on Drug Abuse, U10 “Clinical Trials Network: Texas Node,” $3,550,000

2005-2007 Co-Investigator, National Institute on Alcohol Abuse and Alcoholism. R01. Naltrexone for Bipolar Disorder and Alcohol Dependence,” $275,000 (PI: Brown)

2005–2007 Co-Investigator, National Association for Research of Schizophrenia and Depression (NARSAD), Young Investigator Award "Memory Reconsolidation Interference in PTSD." $120,000 (PI: Alina Suris)

2005 Principal Investigator, Department of Veterans Affairs, Career Development Enhancement Award, “Functional Magnetic Resonance Imaging (fMRI) in the Addictive Disorders,” $80,000.

2004-2009 Principal Investigator, National Institute on Drug Abuse, R25 “Psychiatrist Research Education & Training in Drug Abuse.” $1,400,000

2004-2009 Co-investigator, National Institute on Mental Health, R01 “Stress and Risk for Substance Abuse in Adolescents” $1,250,000 (PI: Uma Rao)

2004-2009 Co-investigator, National Institute on Mental Health, R01 “Neuronal Risk Markers for Nicotine Dependence in Youth” $1,250,000 (PI: Uma Rao)

2003-2005 Principal Investigator, Integrative Neuroscience Initiative on Alcoholism–East, National Institute on Alcohol Abuse and Alcoholism. U01 “fMRI of Stress, HPA Axis, and Limbic Function in Alcoholism.” $100,000

2003-2006 Principal Investigator, National Institute on Drug Abuse, R01 “Limbic Sensitivity in Cocaine Addiction.” (competitive renewal) $750,000

2001-2007 Co-investigator, National Institute on Mental Health, R01 “Risk for Substance Abuse in Depressed Adolescents” $1,500,000 (PI: Uma Rao)

1999-2004 Co-Investigator, National Institute on Drug Abuse, R01 “Cocaine and Sympathetic Nervous Activity in Humans.” $880,000
1999-2000 Principal Investigator, National Institute on Drug Abuse, “Learned Helplessness Model of Cocaine Withdrawal”, $40,000
1998-2003 Principal Investigator, National Institute on Alcohol Abuse and Alcoholism, R01 “Pharmacologic Dissection of the HPA Axis in Alcoholism.” $755,000
1998-2003 Director, Nancy Hogan Boyd Dual Diagnosis Fellowship Program, $120,000
1998-2001 Principal Investigator, National Institute on Drug Abuse, R01 “Limbic Sensitivity in Cocaine Addiction.” $675,000
1996-2001 Participating Investigator, VA Cooperative Study, “Naltrexone in the Treatment of Alcoholism”. $150,964
1998-2003 Co-Investigator, Department of Veterans Affairs, Merit Review “In Vivo Neurochemistry of Stress: Alcohol and Learned Helplessness.” $179,000 (PI: Fred Petty)
1995-1997 Principal Investigator, National Institute on Drug Abuse, R21 “Limbic Sensitivity in Cocaine Addiction.” $104,000
1994-1995 Principal Investigator, MUSC University Research Committee, "Pituitary-Adrenal Axis Disturbances in Alcoholism." $12,000
1992-1997 Co-Investigator, National Institute on Drug Abuse, "Carbamazepine Treatment in Cocaine Abusers," $349,712 (PI: Kathleen Brady)
1993-1994 Co-Investigator, Kabi Pharmacia, "Usefulness of carbohydrate deficient transferrin in monitoring alcohol dependent patients during treatment and/or detoxification." $70,000 (PI: Ray Anton)
1989-1994 On-Site Coordinator, National Institute on Alcohol Abuse and Alcoholism, "Project MATCH: Matching Alcoholics to Client Heterogeneity," $375,385
1988-1991 Principal Investigator, Upjohn, "Double-Blind Drug Study of Ethanol Withdrawal Syndrome," $60,000

Teaching/Education

2017, 2018, 2021, 2022 Invited Mentor, American Psychiatric Association Research Colloquium, (May 21, 2017, San Diego, CA; May 6, 2018, New York City, NY; May 2, 2021, Virtual; May 22, 2022, New Orleans)
2016-2017 Addiction Lectures for MS1-MS2 Class, UT Southwestern Medical Center
2014-2018 Co-director, Dallas Addiction Leadership Training (DALT) Fellowship (VA Interdisciplinary Advanced Fellowship in Addiction Treatment), VA North Texas Health Care System
2007 Course Director, AAAP Review Course in Addiction Psychiatry, Coronado, CA, December 1-2, 2007.
2006 Course Director, AAAP Update in Addiction Psychiatry, Ft. Worth, TX, September 29-30, 2006.
2005 Course Director, AAAP Update in Addiction Psychiatry, San Francisco, CA, February 11-13, 2005, and Atlanta, GA, February 25-27, 2005
2003 Course Co-Director, AAAP Review Course in Addiction Psychiatry, Denver, CO. January 18-19, 2003
2002 Course Director, Annual Addiction Update, NOVA 2002. Dallas, TX. February 22-23, 2002.
2002 Course Co-Director, AAAP Review Course in Addiction Psychiatry, Kansas City, MO. February 2-3, 2002.
2001 Course Co-Director, Annual Addiction Update, NOVA 2001. Dallas, TX. February 14-15, 2001.

2000	Course Co-Director, Annual Addiction Update, NOVA 2000. Dallas, TX. February 4-5, 2000
2000-2018	Associate Director, Addiction Psychiatry Fellowship, UT Southwestern Medical Center
1997-2000	Director, Addiction Psychiatry Fellowship, UT Southwestern Medical Center
1995 -1999	Supervisor, Interdisciplinary Substance Abuse Fellowship Research Project, Dallas VAMC
1993	Physician Planner, Regional Medical Education Center, Department of Veterans Affairs
1992-2007	Clinical supervision of psychiatry residents and medical students
1992-2003	Psychotherapy supervision of psychiatry residents
1992-1993	Supervision of clinical case conferences and inservices for clinical staff and trainees, Substance Abuse Treatment Center, VA Medical Center
1992	Participation in Regional Medical Education Center courses, Veterans Administration
1988-1995	Participation in Substance Abuse Seminar Series, psychiatry residents, Medical Univ South Carolina
1988-1993	Participation in Interviewing Skills Course, 1st year medical students, Medical Univ. South Carolina
1988-1993	Participation in Psychiatry Lecture Series, 3rd year medical students, Medical Univ South Carolina
1988-1995	Primary supervision of Substance Abuse fellows, psychiatry house staff, and medical students at Substance Abuse Treatment Center, VA Medical Center

Honors and Awards

2021	Distinguished Life Fellow, American Psychiatric Association
2017	Distinguished Fellow, American Academy of Addiction Psychiatry (FAAAP)
2012	American College of Neuropsychopharmacology, Fellow
2005	Dr. Kenneth Z. Altshuler Medical Leadership Award, Turtle Creek Manor
2004	American College of Neuropsychopharmacology, Full Member
2002	Alpha Omega Alpha Honor Medical Society Elected Alumnus, College of Human Medicine, Michigan State University
1999-2000	PGY-I Outstanding Teacher of the Year, Psychiatry Residents' Organization Southwestern Medical School
1997	GEICO Public Service Award for the Prevention and Treatment of Substance Abuse
1996-	"Crusader for Prevention", Medical/Health Department; Coalition '96, For Prevention of Substance Abuse; Greater Dallas Council on Alcohol and Drug Abuse
1991-1992	Psychiatry Golden Apple Award, Psychiatry Clerkship, Medical University of South Carolina
1983-1986	NIAAA Fellowship

Non-profit

2023-	President, Doctors for Drug Policy Reform (D4DPR)
2021-	Advisory Council, Kansas Cannabis Coalition
2021-2023	President, Doctors for Cannabis Regulation (DFCR)
2019-2021	Executive Vice President, Doctors for Cannabis Regulation (DFCR)
2018-	Treasurer, Doctors for Cannabis Regulation (DFCR)
2018-	Board of Directors, Doctors for Cannabis Regulation (DFCR)
2017-2018	Co-chair, State Regulatory Committee, Doctors for Cannabis Regulation (DFCR)
2017-	Colorado State Representative, Doctors for Cannabis Regulation (DFCR)
2013-2015	Member, Board of Directors, Mothers Against Teen Violence, Dallas, TX
1998	Moderator and Leadership Panel, Faces of Addiction: A Community Forum. Dallas, TX.
1998	Grand Award Judge, 49th International Science & Engineering Fair, Ft. Worth, TX

1997 Member, Dual Diagnosis Task Force, Dallas, TX
1996-2001 Executive Board of Directors, Greater Dallas Council on Alcohol and Drug Abuse
1996-2001 Chair, Clinical Subcommittee, Greater Dallas Council on Alcohol and Drug Abuse
1995-1997 Scientific Advisor, Chemical Awareness Resources and Education, Park Cities, TX

Outside Interests
Bass Guitar: R/E Authority blues band; Jennifer Rose Band
Advocate Circle, Museum of Contemporary Art, Denver (2021)
Contemporary Collectors Circle, Denver Museum of Art (2019-)
Directors Council, Ft. Worth Museum of Modern Art (2005-2018)
Docent, Ft. Worth Museum of Modern Art (2005-2018)

Peer-Reviewed Articles and Reviews
1. Domino EF, Gahagan S, **Adinoff B**, Kovacic B. Effects of various neuroleptics on rabbit hyperthermia induced by DMT and d-amphetamine. Arch Int Pharmacodyn Ther 226:30-7, March, 1977.
2. Schwartz B, Winstead D, **Adinoff B**: Circumscribed visual processing in schizophrenics. Biol Psychiatry 18:1311-1320, 1983.
3. Zadina J, Kastin A, Coy D, **Adinoff B**: Developmental, behavioral, and opiate receptor changes after prenatal or postnatal B-endorphin, CRF, or Tyr-MIF-1. Psychoneuroendocrinology 10:367-383, 1985.
4. **Adinoff B**, Majchrowicz E, Martin PR, Linnoila M: The benzodiazepine antagonist RO 15-1788 does not antagonize the ethanol withdrawal system. Biol Psychiatry 21:643-649, 1986.
5. Johnson JJ, **Adinoff B**, Bisserbe JC, Martin PR, Rio D, Rohrbaugh JW, Zubovic E, Eckardt M: Assessment of alcoholism-related organic brain syndromes with positron emission tomography. Alcohol Clin Exp Res 10:237-239, 1986.
6. Martin PR, **Adinoff B**, Weingartner H, Mukherjee AB, Eckardt MS: Alcoholic organic brain disease: Nosology and pathophysiologic mechanisms. Prog Neuropsychopharmacol Biol Psychiatry 10:147-164, 1986.
7. Rohrbaugh JW, Stapleton JM, Parasuram R, Zubovic EA, Frowein HW, Varner JL, **Adinoff B**, Lane EA, Eckardt MJ, Linnoila M: Dose-related effects of ethanol on visual sustained attention and event-related potentials. Alcohol 4:293-300, 1987.
8. **Adinoff B**: Hypothalamic-pituitary-adrenal axis functioning in recently abstinent alcoholics. In: M. Linnoila, moderator. Alcohol withdrawal and noradrenergic function. Ann of Intern Med 107:875-889, 1987.
9. Roy A, **Adinoff B**, Roehrich L, Lamparski D, Custer R, Lorenz V, Barbaccia M, Guidotti A, Costa E, Linnoila M: Pathological gambling: A psychobiological study. Arch Gen Psychiatry 45:369-373, 1988.
10. Roy A, **Adinoff B**, Linnoila M: Acting-out in normal volunteers: Negative correlation with 5-HIAA levels. Psychiatry Res 24:187-194, 1988.
11. **Adinoff B**, Bone GHA, Linnoila M: Acute ethanol poisoning and the ethanol withdrawal syndrome. Med Toxicol 3:172-196, 1988.
12. Linnoila M, Oliver J, **Adinoff B**, Potter WZ: High correlations of norepinephrine, dopamine, and epinephrine and their major metabolite excretion rates. Arch Gen Psychiatry 45:701-704, 1988.
13. Rohrbaugh JW, Stapleton JM, Parasuram R, Frowein HW, **Adinoff B**, Varner JL, Lane EA, Eckardt MJ, Linnoila M: Alcohol intoxication reduces visual sustained attention. Psychopharmacol 96:442-446, 1988.
14. George DT, Nutt DJ, Walker WV, Porges SW, **Adinoff B**, Linnoila M: Sodium lactate and hyperventilation substantially attenuate vagal tone in normal volunteers: a possible mechanism of panic provocation? Arch Gen Psychiatry 46:153-156, 1988.

15. Nutt DJ, **Adinoff B**, Ravitz B, George DT, Flowers D, Eckardt M, Bone GHA, Martin PR. Linnoila M: CSF studies in alcoholics and violent offenders. Aust Drug Alcohol Rev 7:105-108, 1988.
16. Martin PR, **Adinoff B**, Eckardt MJ, Stapleton JM, Bone GHA, Rubinow DR, Lane EA, Linnoila M: Effective pharmacotherapy of alcohol amnestic disorder with fluvoxamine: preliminary findings. Arch Gen Psychiatry 46:617-621, 1989.
17. Roy A, DeJong D, Ferraro T, **Adinoff B**, Gold P, Rubinow D, Linnoila M: CSF GABA and neuropeptides in pathological gamblers and normal controls. Psychiatry Res 30:137-144, 1989.
18. Roy A, Lamparski J, De Jong B, **Adinoff B**, Ravitz D, George T, Nutt D, Linnoila M: Cerebrospinal fluid monoamine metabolites in alcoholic patients who attempt suicide. Acta Psychiatr Scand 81:58-61, 1990.
19. **Adinoff B**, Martin PR, Bone GHA, Eckardt MJ, Roehrich L, George DT, Moss H, Eskay R, Linnoila M, Gold PW: Hypothalamic-pituitary-adrenal axis functioning and cerebrospinal fluid CRH and ACTH in alcoholics following recent and long term abstinence. Arch Gen Psychiatry 47:325-330, 1990.
20. Roy A, DeJong J, **Adinoff B**, Linnoila M: CSF galanin in alcoholics, gamblers, and normal controls: A negative report. Biol Psychiatry 15:923-926, 1990.
21. Roy A, DeJong J, **Adinoff B**, Barbaccia M, Costa E, Guidotti A, Linnoila M: CSF diazepam-binding inhibitor in alcoholics and normal controls. Psychiatry Res 31:261-266, 1990.
22. Brady K, Anton R, Ballenger JC, Lydiard RB, **Adinoff B**, Selander J: Cocaine abuse among schizophrenic patients. Am J Psychiatry 147:1164-1167, 1990.
23. Roy A, DeJong J, Ferroro T, **Adinoff B**, Ravitz B, Linnoila M: CSF GABA in alcoholics and controls. Am J Psychiatry 147:1294-1296, 1990.
24. George DT, **Adinoff B**, Ravitz B, Nutt DJ, DeJong J, Berrettini W, Mefford IN, Costa E, Linnoila M: A cerebrospinal fluid study of the pathophysiology of panic disorder associated with alcoholics. Acta Psychiatr Scand 82:1-7, 1990.
25. Roy A, Berrettini W, DeJong J, **Adinoff B**, Ravitz B, Linnoila M: CSF neuropeptide Y in alcoholics and normal controls. Psychiatry Res 33:215-219, 1990.
26. Roy A, Bissette G, Nemeroff C, DeJong J, Ravitz B, **Adinoff B**, Linnoila M: CSF TRH in alcoholics and normal controls. Biol Psychiatry 28:767-72, 1990.
27. Roy A, DeJong J, Ferraro T, **Adinoff B**, Gold P, Rubinow D, Linnoila M: CSF somatostatin, CRH, and ACTH in alcoholics and controls. Acta Psychiatrica Scandinavica. 83:44-48, 1990.
28. Thevos AK, Johnston AL, Latham PK, Randall CL, **Adinoff B**, Malcolm R: Symptoms of anxiety in inpatient alcoholics with and without DSM-III-R anxiety disorders. Alcohol Clin Exp Res 15:102-105, 1991.
29. Roy A, De Jong J, Lamparski D, **Adinoff B**, George T, Moore V, Garnett D, Kerich M, Linnoila M: Mental disorders among alcoholics: Relationship to age of onset and cerebrospinal fluid neuropeptides. Arch Gen Psychiatry 48:423-427, 1991.
30. Limson R, Goldman D, Roy A, Lamparski D, Ravitz B, **Adinoff B**, Linnoila M: Personality and cerebrospinal fluid monoamine metabolites in alcoholics. Arch Gen Psychiatry 48:437-441, 1991.
31. **Adinoff B**, Martin PR, Eckardt MJ, Bone GAH, Gold PW, Linnoila M: Pituitary-adrenal responses to oCRH and central neuropeptide levels in alcoholic amnestic disorder. Biol Psychiatry 29:1153-1155, 1991.
32. **Adinoff B**, Risher-Flowers D, De Jong J, Ravitz B, Bone GHA, Nutt DJ, Roehrich L, Martin PR, Linnoila M: Disturbances of hypothalamic-pituitary-adrenal axis functioning during the ethanol withdrawal syndrome in six men. Am J Psychiatry 148:1023-1025, 1991.
33. **Adinoff B**, Nemeroff CB, Bissette G, Martin PR, Linnoila M: Inverse relationship between CSF TRH concentrations and the TSH response to TRH in abstinent alcoholics. Am J Psychiatry 148:1586-1588, 1991.

34. Roy A, **Adinoff B**, DeJong J, Linnoila M: Cerebrospinal fluid variables among alcoholics lack seasonal variation. Acta Psychiatr Scand 84:579-582, 1991.
35. **Adinoff B**, Mefford I, Waxman R, Linnoila M: Vagal tone decreases following intravenous diazepam. Psychiatry Res 41:89-97, 1992
36. Martin PR, Rio D, **Adinoff B**, Johnson JL, Bisserbe J, Rawlings RR, Rohrbaugh JW, Stapleton JM, Eckardt MJ: Regional cerebral metabolism in chronic organic mental disorders associated with alcoholism. J Neuropsychiatry Clin Neurosci 4:159-167, 1992
37. **Adinoff B**: Long-term therapy with benzodiazepines despite alcohol dependence disorder: Seven case reports. Am J Addictions 1:288-293, 1992
38. **Adinoff B**: Double-blind study of alprazolam, diazepam, clonidine, and placebo in the alcohol withdrawal syndrome. Alcohol Clin Exp Res 18:873-878, 1994
39. **Adinoff B**: The alcohol withdrawal syndrome: Neurobiology of treatment and toxicity. Am J Addictions 3:277-288, 1994
40. **Adinoff B**, O'Neill HK, Ballenger JC: Alcohol withdrawal and limbic kindling: A hypothesis of relapse. Am J Addictions. 4:5-17, 1995
41. Martin P, **Adinoff B**, Lane E, Stapleton J, Bone G, Weingartner H, Linnoila M, Eckardt M: Fluvoxamine treatment of alcoholic amnestic disorder. Eur Neuropsychopharmacol 5:27-33, 1995
42. **Adinoff B**, Kramer G, Petty, F: Levels of gamma-aminobutyric acid in cerebrospinal fluid and plasma during alcohol withdrawal. Psychiatry Res 59:137-144, 1995
43. Brady KT, Sonne S, Randall CL, **Adinoff B**, Malcolm R: Features of cocaine dependence with concurrent alcohol abuse. Drug Alcohol Depend 39:69-71, 1995
44. **Adinoff B**, Anton R, Linnoila M, Guidotti A, Nemeroff C, Bissette G: Cerebrospinal fluid concentrations of corticotrophin-releasing hormone (CRH) and diazepam-binding inhibitor (DBI) during alcohol withdrawal and abstinence. Neuropsychopharmacology. 15:288-295, 1996
45. **Adinoff B**, Kiser, JMC, Martin PR, Linnoila, M: Response of dehydroepiandrosterone to CRH stimulation in alcohol dependent subjects. Biol Psychiatry. 40:1305-1307, 1996
46. **Adinoff B**, Pols B: Dexamethasone in the treatment of the alcohol withdrawal syndrome. Am J Drug Alcohol Abuse 23:615-622, 1997
47. Petty F, Kramer GL, Davis LL, Fulton M, **Adinoff B**: Plasma *g*□aminobutyric acid (GABA) predicts outcome in patients with alcohol dependence. Prog Neuropsychopharmacol Biol Psychiatry 21:809-816, 1997
48. Middaugh LD, McGroatry KK, Groseclose CH, **Adinoff B**. Cocaine discrimination: Relationship to local anesthetics and monoamine uptake inhibitors in C57BL/6 mice. Psychopharmacology 136:44-49, 1998
49. **Adinoff B**, Brady K, Sonne S, Mirabella RF, Kellner CH. Cocaine-like effects of intravenous procaine in cocaine addicts. Addict Biol 3:189-196, 1998
50. Dohoney K, **Adinoff B**. Treatment approaches for the continuum of alcohol-related disorders. JCOM 5:34-44, 1998
51. **Adinoff B**, Dohoney K, Blondell RD. Brief intervention for alcohol problems in primary care: Introduction. JCOM 5:63, 1998
52. **Adinoff B**, Iranmanesh A, Veldhuis J, Fisher L. Disturbances of the stress response during alcohol withdrawal and abstinence: The role of the hypothalamic-pituitary-adrenal axis. Alcohol Health Res World 22:72, 1998
53. Claassen C, **Adinoff B**. Alcohol withdrawal syndrome: Guidelines for management. CNS Drugs. 12:279-291, 1999.
54. Davis LL, Ryan W, **Adinoff B**, Petty F. Comprehensive review of the psychiatric uses of valproate. J Clin Psychopharm. 20:1S-17S, 2000.
55. **Adinoff B**, Devous MD, Best S, George MS, Alexander D, Payne K. Limbic responsiveness following IV procaine in cocaine addiction. Am J Psychiatry 158:390-398, 2001.

56. Brown ES, Suppes T, **Adinoff B**, Thomas NR. Drug abuse and bipolar disorder: comorbidity or misdiagnosis? J Affective Disorders. 65:105-115, 2001.
57. Krystal JH, Cramer JA, Krol WF, Kirk GF, Rosenheck R, VA Naltrexone Cooperative Study 425 Group (**B Adinoff**). Naltrexone in the treatment of alcohol dependence. N Engl J Med 345:1734-9, 2001.
58. **Adinoff B**, Devous MD Sr, Best S, Alexander D, Payne K, Williams M. Dose-response measures of rCBF and subjective changes following procaine in healthy female volunteers. Psy Research: Neuroimaging. 114:123-135, 2002.
59. Gillaspy JA, Wright AR, Campbell C, Stokes S, **Adinoff B**. Group alliance and cohesion as predictors of drug and alcohol abuse treatment. Psychother Res 12:214-229, 2002
60. Cahill MA, **Adinoff B**, Hosig H, Muller K, Pulliam C. Motivation for treatment preceding and following a substance abuse program. Addictive Behaviors. 28:67-79, 2003.
61. **Adinoff B**, Devous MD Sr, Best SE, Chandler P, Alexander D, Payne JK, Harris T, Williams M. Gender difference in limbic responsiveness, by SPECT, in healthy subjects. NeuroImage 18:607-706, 2003
62. **Adinoff B**, Devous MD Sr, Best SE, Harris TS, Chandler P, Frock S, Williams M. Regional cerebral blood flow in female cocaine-addicted subjects following limbic activation. Drug Alcohol Depend 7:255-268, 2003.
63. **Adinoff B**, Devous MD Sr, Cooper DB, Best SE, Chandler P, Harris TS, Cervin CA, Cullum CM. Resting regional cerebral blood flow and Gambling Task performance in cocaine-dependent subjects and healthy comparison subjects. Am J Psychiatry 160:1892-1894, 2003
64. **Adinoff B**, Ruether K, Krebaum S, Iranmanesh A, Williams MJ. Increased salivary cortisol concentrations during chronic alcohol intoxication in a naturalistic clinical sample of men. Alcohol Clin Exp Res 27:1420-1427, 2003
65. **Adinoff B**. Neurobiological processes in drug reward and addiction. Harv Rev Psychiatry. 12:305-320, 2004. (PMC1920543)
66. **Adinoff B**, Krebaum SR, Chandler PA, Ye W, Brown MB, Williams MJ. Dissection of hypothalamic-pituitary-adrenal pathology in one-month abstinent alcohol-dependent men: 1. Adrenocortical and pituitary glucocorticoid responsiveness. Alcohol Clin Exp Res 29:517-527, 2005. (PMC2584970)
67. **Adinoff B**, Krebaum SR, Chandler PA, Ye W, Brown MB, Williams MJ. Dissection of hypothalamic-pituitary-adrenal pathology in one-month abstinent alcohol-dependent men: 2. Response to oCRH and naloxone. Alcohol Clin Exp Res 29:528-537, 2005. (PMC2584970)
68. **Adinoff B**, Junghanns K, Kiefer F, Krishnan-Sarin S. Suppression of the HPA axis stress-response: Implications for relapse. Alcohol Clin Exp Res 29:1351-1355, 2005. (PMC2584966)
69. **Adinoff B**, Williams MJ, Best SE, Harris TS, Chandler P, Devous MD Sr. Sex differences in medial and lateral orbitofrontal cortex hypoperfusion in cocaine-addicted subjects. Gender Med 3:206-222, 2006.
70. Field C, Duncan J, Washington K, **Adinoff B**. Association of baseline characteristics and motivation to change among patients seeking treatment for substance dependence. Drug Alcohol Dep. 91:77-84, 2007.
71. **Adinoff B**, Rilling LM, Williams MJ, Schreffler E, Schepis TS, Rosvall T, Rao U. Impulsivity, neural deficits, and the addictions: The “Oops” factor in relapse. J Addict Dis. 26:25-39, 2007.
72. Schepis T, **Adinoff B**, Rao U. Neurobiological processes in adolescent addictive disorders. Am J Addictions. 17:16-23, 2008. (PMC2274940)
73. Porcu P, O’Buckley TK, Morrow AL, **Adinoff** B. Differential hypothalamic-pituitary-adrenal activation of the neuroactive steroids pregnenolone sulfate and deoxycorticosterone in healthy controls and alcohol-dependent subjects. Psychoneuroendocrinology. 33:214-226, 2008. (PMC2262103)

74. Hardin E, **Adinoff B**. Family history of alcoholism does not influence adrenocortical hyporesponsiveness in abstinent alcohol-dependent men. Am J Drug Alcohol Abuse. 34:151-160, 2008.
75. **Adinoff B**. Divided doses for methadone maintenance (editorial). Am J Psychiatry. 165:303-305, 2008
76. Williams M, **Adinoff B**. The role of acetylcholine in cocaine addiction. Neuropsychopharmacology. 33:1779-1797, 2008. (PMC2667818)
77. Field CA, **Adinoff B**, Harris TB, Ball SA, Carroll KM. Construct, concurrent and predictive validity of the URICA: Data from two multi-site clinical trials. Drug Alcohol Dep. 101:115-23, 2009.
78. **Adinoff B**, Devous MD Sr, Cooper DC, Best SE, Harris TS, Williams M. Neural response to lidocaine in healthy subjects. Psychiatry Res: Neuroimaging. 173:135-142, 2009. (PMC2771760)
79. Brown ES, Carmody TJ, Schmitz JM, Caetano R, **Adinoff B**, Swann AC, Rush AJ. A randomized, double-blind, placebo-controlled pilot study of naltrexone in outpatients with bipolar disorder and alcohol dependence. Alcohol Clin Exp Res. 33:1863-9, 2009.
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82. **Adinoff B**, Devous MD Sr, Williams MJ, Best SE, Harris TS, Minhajuddin A, Zielinski T, Cullum M. Altered neural cholinergic receptor systems in cocaine-addicted subjects. Neuropsychopharm. 35:1485-1499, 2010. (PMC3055466)
83. **Adinoff B**, Best SE, Ye W, Williams MJ, Iranmanesh A. Adrenocortical and pituitary glucocorticoid feedback in abstinent alcohol-dependent women. Alcohol Clin Exp Res. 34:915-24, 2010. ePub 2010 Mar 10.
84. Kourosh AS, Harrington CR, **Adinoff B**. Tanning as a behavioral addiction. Am J Drug Alcohol Abuse. 36:284-90, 2010. Epub 2010 June 15.
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87. Schepis T, Rao U, **Adinoff B**. The limbic-hypothalamic-pituitary-adrenal axis and the development of alcohol use disorders in youth. Alcohol Clin Exp Res. 35:1-11, 2011. ePub 2011 Jan 11. (PMC3074933)
88. Harrington CR, Beswick TC, Leitenberger J, Minhajuddin A, Jacobe HT, **Adinoff B**. Addictive-like behaviors to ultraviolet light in frequent indoor tanners. Clin Exp Dermatol. 36:33-8, 2011. ePub 2010 June 7.
89. Harrington CR, Beswick TC, Graves M, Jacobe HT, Harris TS, Kourosh S, Devous MD, **Adinoff B**. Activation of mesostriatal reward pathway with exposure to ultraviolet radiation (UVR) vs. sham UVR in frequent tanner: a pilot study. Addict Biol. 17:680-6, 2012. ePub 2011 April 11.
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91. Tamm L, **Adinoff B**, Nakonezny PA, Winhusen T, Riggs PD. Attention-deficit/hyperactivity disorder subtypes in adolescents with comorbid substance-use disorder. Am J Drug Alcohol Abuse. 38:93-100, 2012. Epub 2011 Aug 11. (PMC3441182)

92. Bobb DS Jr, **Adinoff B**, Huang H, Laken SJ, McClintock SM, Rubia K, Husain MM, Mapes, KS, Tamminga C, Cullum CM, Gopinath K, Trivedi MH, Kozel FA. Neural correlates of successful response inhibition in unmedicated patients with late life depression. Am J of Geriatric Psychiatry. 20:1057-69, 2012. Epub 2011 Oct 15.
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96. Liu P, Uh J, Devous MD, **Adinoff B**, Lu H. Comparison of relative CBF maps using pseudo-continuous ASL and SPECT. Biomedicine. 25:779-786, 2012. Epub 2011 Dec 6. (PMC3298573)
97. Winhusen T, Stitzer M, Woody G, Brigham G, Kropp F, Ghitza U, Lindblad R, **Adinoff B**, Green C, Sharma G, Somoza E. Design considerations for a study to evaluate the impact of smoking cessation treatment on stimulant use outcomes in stimulant-dependent individuals. Contemp Clin Trials. 33:197-205, 2012. ePub 2011 Oct 8. (PMC3253873)
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99. Yang H, Spence JS, Devous MD, Briggs RW, Goyal A, Xiao H, Yadav H, **Adinoff B**. Striatal-limbic activation is associated with intensity of anticipatory anxiety. Psychiatry Res: Neuroimaging 204:123-131, 2012. ePub 2012 Nov 6. (PMC3562596)
100. Donovan DM, Bogenshultz MP, Perl H, Forcehimes A, **Adinoff B**, Mandler R, Oden N, Walker NR. Study design to examine the potential role of assessment reactivity in the screening, motivational assessment, referral and treatment in emergency departments (SMART-ED) Protocol. Addict Sci Clin Pract. 7:16, 2012. (PMC3599426);
101. Winhusen T, Brady K, Stitzer M, Woody, G, Lindblad R, Kropp F, Brigham G, Liu D, Sparenborg S, Sharma G, VanVeldhuisen P, **Adinoff B**, Somoza E. Evaluation of buspirone for relapse-prevention in adults with cocaine dependence: An efficacy trial conducted in the real world. Contemp Clin Trials. 33:993-1002, 2012. ePub 2012 May 19. (PMC3408816)
102. Winhusen TM, Somoza EC, Lewis DF, Kropp FB, Horigian VE, **Adinoff B**. Frontal systems deficits in stimulant-dependent patients: Evidence of pre-illness dysfunction and relationship to treatment response. Drug Alcohol Dep. 127:94-100, 2013. ePub 2012 Jul 6. (PMC3470826)
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104. Winhusen TM, Lewis D, **Adinoff B**, Brigham G, Kropp F, Donovan DM, Seamans CL, Hodgkins CC, DiCenzo JC, Botero CL, Jones DR, Somoza E. Impulsivity is associated with treatment non-completion in cocaine- and methamphetamine-dependent patients but differs in nature as a function of stimulant-dependence diagnosis. J Subst Abuse Treat. 44:541-7, 2013. ePub 2013 Jan 7. (PMC3602401)
105. **Adinoff B**, Conley RR, Taylor SF, Chezem LL. Protecting confidentiality in human research. Am J Psychiatry. 170:466-470, 2013.
106. Burdick BV, **Adinoff B**. A proposal to evaluate mechanistic efficacy of hallucinogens in addiction treatment. Am J Drug Alcohol Abuse. 39:291-7, 2013. ePub 2013 Aug 22.

107. North CS, **Adinoff B**, Pollio DE, Kinge S, Downs DL, Pfefferbaum B. Alcohol use disorders and drinking among survivors of the 9/11 attacks on the World Trade Center in New York City. Compr Psychiatry. 54(7):962-9, 2013. ePub 2013 May 1.
108. Yang H, Devous MD, Briggs RW, Spence JS, Xiao H, **Adinoff B**. Altered neural processing of threat in alcohol-dependent men. Alcohol Clin Exp Res. 37(12):2029-38, 2013. ePub 2013 Jul 24. (PMC4038904)
109. Winhusen TM, **Adinoff B**, Lewis DF, Brigham GS, Gardin JG, Sonne SC, Theobald J, Ghitza U. A tale of two stimulants: mentholated cigarettes may play a role in cocaine, but not methamphetamine, dependence. Drug Alcohol Dep. 133(3):845-51, 2013. ePub 2013 Sept 11.(PMC3889716)
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"The Addicted Brain Knows No Fear: Findings from Neuroimaging Studies." *Keynote Speaker, 29th Annual Institute on Substance Abuse and Addiction*. Lubbock, TX. March 22, 2007.

"The Re-Wired Brain: Neuroimaging Studies in Addicted Patients." *VISN 23 Mental Health Conference.* Minneapolis, MN. May 3, 2007.

"Suppressed-Stress Response in Alcoholism: A Biological Disturbance in Search of Meaning." *Grand Rounds.* Department of Psychiatry, Medical University of South Carolina, Charleston, SC. Sep. 14, 2007.

"Translating Drug Abuse Research Into Practice: The NIDA Clinical Trials Network – The Texas Node." *Grand Rounds.* University of Texas Southwestern Medical Center. Dallas, TX. Oct. 17, 2007.

"Trauma and Alcoholism: The Stress Hormone Link?" *Grand Rounds.* Department of Psychiatry, University of New Mexico. Oct. 24, 2008.

"Trauma, Stress, Alcohol, Genes and HPA Axis Disruptions: Is There An Additive Link?" *Distinguished Speaker Seminar*, Department of Clinical Sciences, UT Southwestern Medical Center, Dallas, TX. Feb. 12, 2008.

"Impulsivity: What Is It, Who Has It, and What To Do About It." *2009 Update in Psychiatry: Common Challenges in Psychopharmacology*. Medical University of South Carolina, Charleston, SC. May 30, 2009.

"Impulsivity in the Addictive Disorders: The "Oops" Factor in Relapse." *Grand Rounds.* Department of Psychiatry, Vanderbilt University, Nashville, TN. Jan. 7, 2010.

"The Re-wired Addicted Brain: Why It's Hard to Stop Using Nicotine, Alcohol and Other Drugs" *Grand Rounds.* Methodist Hospital Center, Dallas, TX. Feb. 4, 2010.

"Trauma, Alcoholism, and Stress-Hormone Disruptions." *Grand Rounds.* John Peter Smith Hospital, Ft. Worth, TX. March 26, 2010

"Translational Studies in Addicted Subjects: An Exploration of Non-dopaminergic Systems." Seminar, Department of Pharmacology and Neuroscience. University of North Texas Health Science Center. Ft. Worth, TX. March 30, 2010

"Drug Use Without Craving: Impulsive Relapse in Addiction." *Grand Rounds,* Department of Neuropsychiatry and Behavioral Science, Texas Tech University Health Science Center. Lubbock, TX. March 29, 2011.

"Shared Cortical-Limbic-Striatal Disruptions in Human Imaging Studies of Addiction." UTD 2012 Neuroscience Research Conference. Dallas, TX. April 13, 2012.

"Clinical and Neurobiological Aspects of Impulsive Relapse." Continuing Educational (CE) program. Hazeldon Foundation. Center City, MN. July 18, 2012.

"Neuroimaging in Addiction: Common Threads." *Grand Rounds*. Seton Medical Center. Austin, TX. Aug. 14, 2012.

"Neuroimaging in the Investigation and Assessment of Substance Use Disorders." Texas Society of Psychiatric Physicians 56th Annual Convention. Galveston, TX. Nov. 10, 2012.

"Cravings, Memories, and Addiction: A Critical Role for the Hippocampus?" *Grand Rounds*. Center for BrainHealth, University of Texas at Dallas. May 1, 2013.

"Does Stress Really Make You Drink? The Biological Connection." *Grand Rounds*. Department of Psychiatry, UT Southwestern Medical Center. Dallas, TX. May 8, 2013.

"DSM-5: Substance Use Disorders." Continuing Education Symposium. Department of Psychiatry, UT Southwestern Medical Center. Dallas, TX. July 20, 2013.

"DSM-5: Substance Use Disorders." VA North Texas Health Care System. Dallas, TX. July 26, 2013. August 9, 2013.

"Use of Certificate of Confidentiality (COC)." *Research Matters.* UT Southwestern Medical Center. Dallas, TX. April 2, 2014.

"Does Stress Make You Drink?" *Grand Rounds.* Mental Health, VA North Texas Health Care System. Dallas, TX. July 17, 2014.

"What More is Needed to Prove UV Radiation is Rewarding and Addictive." *Grand Rounds.* Department of Dermatology, UT Southwestern Medical Center. August 14, 2014.

"What We're Learning About the Neuroscience of Addiction". *Reinvesting in Justice: What Comes Next?* Center for Court Innovation. Dallas, TX. November 12, 2015

"Pharmacotherapy for Alcohol Use Disorders" Symposium on *Medication as an adjunct versus monotherapy for the treatment of substance use disorders*. Texas Research Society on Alcoholism, Dallas, TX. February 19, 2016.

"Pharmacology for Alcohol Use Disorders" Symposium on *Alcohol Use Disorders* (Moderator). Texas Society of Psychiatric Physicians & Texas Academy of Psychiatry. Austin, TX May 7, 2016.
"Naloxone Rescue" Symposium on *The epidemic of opioid and alcohol use disorders in America today*" Texas Society of Psychiatric Physicians & Texas Academy of Psychiatry. Austin, TX May 6, 2016.
"The Addiction Brain" *Psychiatry CME Event: Substance Use Treatment for the General Provider.* Department of Psychiatry, UT Southwestern, Dallas, TX. May 21, 2016
"Practical & Effective Pharmacotherapy for Alcohol Use Disorders" *Grand Rounds*. Trinity Springs/John Peter Smith Hospital. July 15, 2016.
"Biological stress reactivity and alcohol use disorders – from early intramural NIAAA to the present." Special Interest Group on Psychoneuroendocrinology. NIH Clinical Center, Bethesda, MD. April 25, 2017.
"Biological stress reactivity and alcohol use disorders – from early intramural NIAAA to the present." NIAAA Intramural Research Seminar Series. Bethesda, MD. April 26, 2017.
"Cravings, Memories, and Addiction: A Critical Role for the Hippocampus?" Neuroimaging Research Branch, NIDA. Baltimore, MD. April 26, 2017.
"Pharmacotherapy for Substance Use Disorders". Family Medicine Residents, UT Southwestern Medical Center, March 7, 2017. Baylor Scott & White Family Practice Residents. Baylor Medical Center. Garland, TX. August 10, 2017. Internal Medicine Grand Rounds, Dallas Methodist Medical Center, Dallas, TX. Sept. 7, 2017.
"Alcohol." *Review Course on Addiction Psychiatry/Addictions and Their Treatment*. American Academy of Addiction Psychiatry. Amelia Island. December 3, 1995; San Francisco, CA. December 8, 1996; Kansas City, MO. February 8, 1998; Denver, CO. January 18, 2003; Atlanta, GA. Feb. 26, 2005. Coronado, CA. December 1, 2007; Baco Raton, FL. December 8, 2008; Hollywood, CA. December 6, 2009; Scottsdale, AZ. June 12, 2010; Boca Raton, FL. December 5, 2010; Scottsdale, AZ. Dec. 10, 2011. Scottsdale, AZ. December 4, 2013; Aventura, FL. December 3, 2014; Huntington Beach, CA. December 3, 2015; Bonita Springs, FL. December 8, 2016; Palm Desert, CA. December 7, 2017; Bonita Spring, FL. December 6, 2018; San Diego, CA. Dec 5, 2019; Virtual, Oct 3, 2020; Virtual, Oct 1, 2021.
"The legacy of physician support for cannabis prohibition: A reckoning with our past and how to move forward." 4th Annual Medical Cannabis Conference. Charleston, SC (virtual) Jan 28, 2022
"Drug criminalization and cannabis use and misuse: An ethical dilemma for physicians." Psychiatry Grand Rounds. John Peter Smith Hospital. Ft. Worth, TX. (virtual) Feb 4, 2022

Symposiums/Workshops at National and International Conferences

Adinoff B (chair). Symposium on *New pharmacologic approaches for detoxification*. American Psychiatric Association 145th Annual Meeting. Washington, DC, May 4, 1992.
Adinoff B, Linnoila M, Anton R. "Alprazolam and clonidine in alcohol withdrawal." Symposium on *New pharmacologic approaches for detoxification.* American Psychiatric Association 145th Annual Meeting. Washington, DC, May 4, 1992.
Adinoff B. "Pharmacotherapy of alcohol and sedative dependence: Neurobiologic implications." Symposium on *The Pharmacology of Drug Dependence*. Fourth Annual Symposium of the American Academy of Psychiatrists in Alcoholism and Addictions. West Palm Beach, FL, December 5, 1993.
O'Brien CP, Adinoff B, Rosman A, Smith D. Workshop on *Advances in Veterans Affairs Psychiatry Research*. American Psychiatric Association Annual Meeting. Philadelphia, PA, May 23, 1994.
Adinoff, B (Chair). Symposium on *Neuroimaging in Cocaine Addicts.* 54th Annual Convention of the Society of Biological Psychiatry, Washington, D.C. May 14, 1999
Adinoff B, Devous MD, Best S, George MS, Alexander D, Payne K: "IV procaine and limbic activation (SPECT) in cocaine addiction" in Symposium on *Neuroimaging in Cocaine Addicts.* 54th Annual Convention of the Society of Biological Psychiatry, Washington, D.C. May 14, 1999

Adinoff B, Devous MD, Sr., Best SM, George MS, Alexander D, Payne KJ. "Orbitofrontal dysfunction in cocaine addiction: SPECT following IV procaine." Symposium on *Addiction as a Disease of the Orbitofrontal Cortex.* 39th ACNP Annual Meeting, San Juan, Puerto Rico. December 11, 2000.

Adinoff B (Chair), Porrino L, Anton R, London E. Symposium on *The orbitofrontal cortex and the addictions: Neuroimaging studies.* Thirty-fourth Annual Winter Conference on Brain Research. Steamboat Springs, CO. January 20-27, 2001.

Adinoff B. (Co-Chair). Symposium on *What the General Psychiatrist Needs to Know about Addiction Psychiatry.* American Psychiatric Association 2003 Annual Meeting, May 20, 2003. San Francisco, CA

Adinoff B., "Neuroscience of addictions" in Symposium on *What the General Psychiatrist Needs to Know about Addiction Psychiatry.* American Psychiatric Association 2003 Annual Meeting, May 20, 2003. San Francisco, CA

Adinoff B. (Chair). Symposium on *Stress-Axis Reactivity to Pharmacologic Challenges: Defining the Disruption in the Drinkers and the Kids.* 26th Annual Meeting of the Research Society on Alcoholism. June 22, 2003. Ft. Lauderdale, FL.

Adinoff, B. "HPA axis sensitivity in abstinent alcohol dependent subjects: Isolation of axis pathology". Symposium on *Stress-Axis Reactivity to Pharmacologic Challenges: Defining the Disruption in the Drinkers and the Kids.* 26th Annual Meeting of the Research Society on Alcoholism. June 22, 2003. Ft. Lauderdale, FL.

Adinoff B (Chair). Symposium on *Sex Differences in the Addicted Brain: Neuroimaging Studies of Cocaine- and Alcohol-Dependent Men and Women*. College on Problems on Drug Dependence Sixty-fifth Annual Scientific Meeting, Bal Harbour, FL. June 16, 2003.

Adinoff B. (Chair). "Differing limbic sensitivity to a pharmacologic stimulus in cocaine-addicted men and women". Symposium on *Sex Differences in the Addicted Brain: Neuroimaging Studies of Cocaine- and Alcohol-Dependent Men and Women*. College on Problems on Drug Dependence Sixty-fifth Annual Scientific Meeting, Bal Harbour, FL. June 16, 2003.

Adinoff B (Co-Chair). Symposium on *Neuroimaging the Contrast: Cocaine Addicted Men vs. Women.* American College of Neuropsychopharmacology 42nd Annual Meeting. San Juan, Puerto Rico. Dec. 10, 2003.

Adinoff B., Devous M., Best SE., Harris TS. "Sex differences in limbic rCBF following both a saline and procaine stimulus in cocaine-addicted subjects". Symposium on *Neuroimaging the Contrast: Cocaine Addicted Men vs. Women.* American College of Neuropsychopharmacology 42nd Annual Meeting. San Juan, Puerto Rico. Dec. 10, 2003.

Adinoff B. (Chair). Symposium on *Suppression of the HPA Axis Stress-Response: Implications for Relapse.* 12th World Congress on Biomedical Alcohol Research (ISBRA). Heidelberg/Mannheim, Germany. Oct. 1, 2004.

Adinoff B. Krebaum S, Chandler P, Ye W. Brown MB, Williams M.J. "Blunted adrenocortical responsiveness in abstinent alcohol-dependent men". Symposium on *Suppression of the HPA Axis Stress-Response: Implications for Relapse.* 12th World Congress on Biomedical Alcohol Research (ISBRA). Heidelberg/Mannheim, Germany. Oct. 1, 2004.

Adinoff B. "Impulsivity and Relapse." Symposium on *Addiction and Psychiatry: Co-Occurring or Dual Diagnosis.* 36th Annual Medical-Scientific Conference. American Society of Addiction Medicine. Dallas, TX. April 16, 2005.

Adinoff B, Morrow AL, Williams MJ, Chandler PA. "oCRF stimulation of plasma deoxycorticosterone levels in abstinent alcohol-dependent subjects." Symposium on *Are Neurosteroid Responses to Stress or Alcohol Withdrawal Related to Alcohol Drinking - In Mouse, Rats, Monkeys or Man?* 29th Annual Meeting of the Research Society on Alcoholism. Baltimore, MD. June 27, 2006

Adinoff B (chair): Symposium on *The Yin to the Dopaminergic Yang: Cholinergic Mechanisms in Cocaine Addiction*. 40th Annual Winter Conference on Brain Research. Snowmass, Colorado, February 1, 2007.

Adinoff B (chair): Symposium on *Assessing Stress in Alcoholics using Clinical Laboratory Paradigms*. Research Society on Alcoholism, Chicago, IL. July 9, 2007.

Adinoff B. "It's not a perfect world: A clinical researcher's perspective." Symposium on *Translating Research: Basic and Clinical Dialogues.* Research Society on Alcoholism, Chicago, IL. July 9, 2007.

Sinha R, Wu H, Goeders NE, Adinoff B, Weiss F. Symposium on *Organizing a Special Interest Group on Stress and Addiction.* College on Problems on Drug Dependence Seventieth Annual Scientific Meeting. San Juan, Puerto Rico. June 15, 2008.

Adinoff B. "Limbic disruptions identified by cholinergic probes in cocaine-addicted subjects." Symposium on *The Acetylcholine System as Therapeutic in Drug Dependence.* College on Problems on Drug Dependence 71st Annual Scientific Meeting. Reno, Nevada. June 23, 2009.

Adinoff B. "Results from naturalistic and epidemiologic studies." Workshop on *Is the Emperor Underdressed? Controversial Evidence that Alcohol Induces Drinking*. Research Society on Alcoholism, San Antonio, TX. June 28, 2010.

Adinoff B. "Limbic disruptions identified by cholinergic probes in cocaine-addicted subjects." Symposium on *Cholinergic Mechanisms in Stimulant Dependence.* Translational Psychiatry 1st Annual Scientific Meeting. Hall, Austria. July 10, 2010.

Adinoff B, Taylor S, Conley R, Chezum L. "The certificate of confidentiality: Is the hassle worth it?" Symposium on *Negotiating the Path to Approval: Finding Solutions to Common IRB Issues*. ACNP 49th Annual Meeting. Miami, FL. Dec 8, 2010.

Denton W, Winhusen T, Lewis D, Walker NR, Adinoff B. "Family discord is associated with increased substance use for pregnant substance users." International Association for Relationship Research Mini-Conference on Health, Emotions and Relationships. Tucson, AZ. October 20-22, 2011.

Adinoff B. (Chair) Symposium on *Stress, Arousal and Alcohol Interactions: Clinical Studies in High-Risk Adolescents, Healthy Adults and Alcohol-Dependent Subjects*. Alcoholism and stress: A framework for future treatment strategies. Volterra, Italy. May 5, 2011.

Adinoff B, Yang H, Rao U, North CS, Xiao H, Business MS. "Unraveling the risks: Stress, trauma and alcohol effects upon biologic stress response systems and prospective relapse in alcohol dependent subjects". Symposium on *Stress, Arousal and Alcohol Interactions: Clinical Studies in High-Risk Adolescents, Healthy Adults and Alcohol-Dependent Subjects*. Alcoholism and Stress: A Framework for Future Treatment Strategies. Volterra, Italy. May 5, 2011.

Adinoff B. "Stress, trauma and alcohol effects upon biological stress response systems and prospective relapse in alcohol dependent subjects." Symposium on *Clinical Translational Research Linking the Neurobiology of Dysregulated Stress/Anxiety Systems to Alcohol Use Disorders.* Research Society on Alcoholism. San Francisco, CA. July 26, 2012.

Adinoff B. "Striatal-limbic suppression during anticipatory anxiety in alcohol-dependent men". Symposium on *Applying Translational Research and Imaging to Treatment Strategies in Alcoholism.* American College on Neuropsychopharmacology 51st Annual Meeting. Hollywood, FL. December 3, 2012.

Price JL, Leonard D, Adinoff B. HPA Axis Dysfunction and Stress Implications in Relapse Severity. Symposium presented at the *24th Annual Scientific Meeting of the Texas Research Society on Alcoholism*, San Antonio, TX. February 21, 2014.

Adinoff B. Discussant. Symposium on *Functionally relevant brain alterations in poly-substance abusers: Differences to mono-substance abusers, study challenges and research promises.* Research Society on Alcoholism. San Antonio, TX. June 21, 2015

Lewis B, Price JL, Adinoff B, Nixon SJ. "Exploring heterogeneity in the stress-alcohol diathesis across the lifespan." Organizer: Dr. Sara Jo Nixon. 4th Annual International Congress on Alcoholism and Stress, Volterra, Italy (May 9-12, 2017)

Price JL, Frazier IR, Javors MA, Walker R, Nixon SJ, Adinoff B. Differences in HPA Function Between Black and White alcohol-dependent men. Organizer: Awards Committee. Symposium presented at

the *40th Annual Meeting of the Research Society on Alcoholism (RSA)*, Denver, CO. June 24-28, 2017.

Adinoff B. Discussant. Symposium on *Drug Addiction Treatment with Classic Hallucinogens*. CPDD 80th Annual Scientific Meeting, San Diego, CA. June 11, 2018.

Adinoff B. Chair and Discussant. Symposium on *A New Era of Treating Substance Use Disorders with Psychedelics*. AAAP Annual Meeting and Scientific Symposium. Bonita Springs, FL. December 6, 2018.

Adinoff B. Chair. Symposium on *Medical Cannabis from a Neuroscience Perspective: How Did We Get Here and Where Should We Go?* American College on Neuropsychopharmacology 57st Annual Meeting. Hollywood, FL. December 12, 2018.

Adinoff B. Maximizing the benefits and minimizing the harms of cannabis regulation. Symposium on *Perspective on the Impact on Adolescents and Emerging Adults of Marijuana's Changing Legal Status and Access.* Chair: Theodore Petti. 66th Annual Meeting of the American Academy of Child and Adolescent Psychiatry. Chicago, IL. Oct 19, 2019.

Adinoff B. Chair. Symposium on *The Racial Origins and Impact of the War on Drugs: How Do We Heal?* AAAP Annual Meeting and Scientific Symposium. Virtual. December 12, 2021.

Adinoff B. The role of addiction psychiatrists in righting the wrongs of the drug war. Symposium on *The Racial Origins and Impact of the War on Drugs: How Do We Heal?* AAAP Annual Meeting and Scientific Symposium. Virtual. December 12, 2021.

Adinoff B. Chair. Symposium on *Treating Substance Use Disorders with Classical Psychedelics*. American Psychiatric Association Annual Meeting. New Orleans, LA. May 24, 2022.

Adinoff B. Panel on *Cannabis Law Reform leading the way towards more effective drug control and the attainment of the Sustainable Development Goals*. United Nations 66th Commission on Narcotic Drugs (CND). Vienna, Austria. March 15, 2023.

Adinoff B. Chair. Symposium on *The Racist Origins and Impact of the War on Drugs.* CPDD 85th Annual Scientific Meeting, Denver, CO. June 20, 2023.

Adinoff B. The role of addiction researchers in righting the wrongs of the drug war. Symposium on *The Racist Origins and Impact of the War on Drugs.* CPDD 85th Annual Scientific Meeting, Denver, CO. June 20, 2023.

Other Presentations

Heath RG, Franklin D, Adinoff B, Rubin W. "Comparison of schizophrenics with and without cerebellar vermal atrophy." Society of Biological Psychiatry, Boston, MA, May 18, 1980.

Adinoff B, Majchrowicz E, Martin PR, Paul SM, Linnoila M. "The benzodiazepine antagonist Ro15-1788 does not antagonize ethanol withdrawal syndrome." Society of Biological Psychiatry, Dallas, TX, 1985.

Adinoff B, Martin PR, Bone GHA, Linnoila M, Gold PW. "Response to corticotropin releasing factor in alcoholics one and three weeks following cessation of drinking." American Psychiatric Association 139th Annual Meeting, Washington, DC, May 13, 1986.

Adinoff B, Rohrbaugh JW, Stapleton JM, Parasuraman R, Frowein HW, Varner JL, Lane EA, Eckardt MJ, Linnoila M. "Alcohol intoxication reduces visual sustained attention." American College of Neuropsychopharmacology, Washington, DC, December 11, 1986.

Adinoff B, Dave JR, Roehrich L, Martin PR, George T, Eskay R, Linnoila M. "Corticotrophin-releasing hormone binding sites on RBCs in alcoholics, children at risk, and normal controls." Collegium International Neuro-Psychopharmacologicum, San Juan, Puerto Rico, December 17, 1986.

Stapleton JM, Eckardt P, Adinoff B, Roehrich L, Bone G, Rubinow D, Mefford I, Linnoila M. "Treatment of alcoholic organic brain syndrome with the serotonin reuptake inhibitor, fluvoxamine: Relationships between neurochemical and neuropsychological responses." Research Society on Alcoholism/Committee on Problems of Drug Dependence, Philadelphia, 1987.

Collins MT, Karanian JW, Adinoff BH, Dave JR. "Effects of in vivo and in vitro alcohol exposure on corticotropin-releasing factor (CRF) binding to rat erythrocyte membranes." Federation of the American Society of Experimental Biologist. Washington D.C., 1987.

Matsuo V, Weingartner H, Adinoff B, Linnoila M, Paul S, Hommer D. "Effects of diazepam on human saccadic eye velocity: Antagonism by Ro 15-1788 and increased sensitivity in chronic alcoholics." Society for Neuroscience. Washington, D.C., 1987.

Martin PR, Adinoff B, Bone GHA, Stapleton JM, Eckardt MJ, Linnoila M. "Fluvoxamine treatment of alcoholic chronic organic brain syndromes." American Society for Clinical Pharmacology and Therapeutics. Orlando, Florida, 1987.

Roy A, Adinoff B, Roehrich L, Lamparski D, Custer R, Lorenz V, Linnoila M. "A search for biological substrates to pathological gambling." Proceedings of the 4th International Conference on Gambling and Risk-taking. Nevada, 1987.

Adinoff B, Risher-Flowers D, Ravitz B, Bone GHA, Nutt D, Martin PR, Linnoila M. "Circadian rhythms of cortisol during alcohol withdrawal." American College of Neuropsychopharmacology, San Juan, Puerto Rico, 1987.

Adinoff B, Martin PR, Bone GHA, Eckardt MJ, Linnoila M, Gold P. "Corticotrophin-releasing hormone stimulating test and CSF neuropeptides in abstinent alcoholics, alcohol-induced organic brain syndrome, and controls." American Psychiatric Association 141st Annual Meeting, Montreal, May 12, 1988.

Roy A, Adinoff B, Roehrich L, Lamparksi D, Custer RL, Linnoila M. "Neurobiology of gambling." American Psychiatric Association 141st Annual Meeting, Montreal, Canada, May 11, 1988.

Adinoff B. "Saccadic eye velocity following intravenous diazepam." Department of Psychiatry and Behavioral Sciences Research Seminar, Medical University of South Carolina. Charleston, SC, October 17, 1988.

Adinoff B, Hommer D, Clem T, Moran J, Paul SM, Linnoila, M. "Alcoholics' sensitivity to intravenous diazepam." American Psychiatric Association 142nd Annual Meeting, San Francisco, CA, May 11, 1989.

Brady KT, Selander J, Lydiard RB, Anton R, Ballenger JC, Adinoff B. "Cocaine abuse in schizophrenia." American College of Neuropsychopharmacology, Maui, Hawaii. December 11, 1989.

Roy A, Adinoff B, Gold P, Rubinow D, Linnoila M. "CSF somatostatin, CRH, and ACTH in alcoholics and controls." Society of Biological Psychiatry, New York, May, 1990.

Roy A, Berrettini W, DeJong J, Adinoff B, Ravitz B, Linnoila M. "CSF neuropeptide Y and growth hormone releasing hormone in alcoholics and normal controls." Society of Biological Psychiatry, New Orleans, 1991.

Roy A, DeJong J, Lamparski D, Adinoff B, George T, Linnoila M. "Age of onset alcoholism." American Psychiatric Association 144th Annual Meeting. New Orleans, LA, May 11, 1991.

Adinoff B, Linnoila M, Bisette G, Guidotti A, Mefford I, Nemeroff CB. "Cerebrospinal fluid concentrations of CRH, DBI, and catecholamine metabolites during alcohol withdrawal and abstinence." American College of Neuropsychopharmacology. San Juan, Puerto Rico, December 14, 1992.

Brady KT, Sonne S, Randall CL, Adinoff B. "Features of cocaine dependence with concurrent alcohol abuse." American College of Neuropsychopharmacology. San Juan, Puerto Rico, December, 1993.

Adinoff B, Brady K, Sonne S, Kellner C. "Limbic activation by IV procaine in cocaine addicts." College on Problems of Drug Dependence. Palm Beach, FL, June 20, 1994.

Adinoff B Cantey JM, Martin PR, Linnoila M. "Response of dehydroepiandrosterone to CRH stimulation in alcohol dependent subjects." International Society of Psychoneuroendocrinology. Seattle, Washington, August 14, 1994.

Adinoff B. "SPECT following IV procaine in cocaine addiction." Thirty-first Annual Winter Conference on Brain Research. Snowbird, Utah, January 26, 1998.

Adinoff B, Devous MD, Best S, George MS, Alexander D, Payne K. "SPECT following intravenous procaine in cocaine addiction." Advancing from the Ventral Striatum to the Extended Amygdala: Implications for Neuropsychiatry and Drug Abuse. NYAS Conference, Oct. 19, 1998.

Adinoff B. "Recovery of the Hypothalamic-pituitary-adrenal axis with abstinence." 1999 Scientific Meeting of the Research Society on Alcoholism. Santa Barbara, CA. June 27, 1999.

Colwell K, Edens JF, Willoughby FW, Adinoff B, Houser L. "Assessing motivation to change among substance abusers." 108th Annual Conference of the American Psychological Association. Washington, DC. August, 2000.

Adinoff B, Krebaum S, Chandler PA, Veldhuis JD, Iranmanesh A. "Dissection of HPA axis disturbances in abstinent alcohol dependent subjects." 57th Annual Convention of the Society of Biological Psychiatry, Philadelphia, PA. Ma7 18, 2002.

Krebaum SR, Jackley PK, Adinoff B. "The Impulsive Relapse Questionnaire: A measure of automaticity in substance dependence." 64th Annual Scientific Meeting of the College on Problems of Drug Dependence. Quebec City, Canada. June 10, 2002

Adinoff B, Devous MD Sr, Cooper DB, Best SE, Chandler P, Harris T, Cervin CA, Cullum M. "Relationship between rCBF (by SPECT) and gambling task performance in cocaine addicted subjects and controls." 64th Annual Scientific Meeting of the College on Problems of Drug Dependence. Quebec City, Canada. June 12, 2002.

Krebaum SR, Jackley PK, Adinoff B. "The Impulsive Relapse Questionnaire: Development and validation." 2002 Scientific Meeting of the Research Society on Alcoholism and the 11th Congress of the International Society for Biomedical Research on Alcoholism. San Francisco, CA. June 29, 2002.

Jackley PK, Krebaum SR, Adinoff B. "The Impulsive Relapse Questionnaire (IRQ): A measure of automaticity in substance dependence." ACNP 41st Annual Meeting, Dec. 10, 2002

Adinoff B, Devous MD Sr., Best SE, Chandler P, Harris TS, Williams M. "Pharmacologic limbic activation in abstinent cocaine-dependent subjects." ACNP 41st Annual Meeting, Dec. 10, 2002

Adinoff B, Devous MD Sr, Williams MJ, Best SE, Zielinski T, Harris TS, Schreffler ER. "Differences in rCBF Response between Abstinent Cocaine-addicted Subjects and Healthy Controls to the 5HT3 Antagonist, Ondansetron." American College of Neuropsychopharmacology 43rd Annual Meeting. San Juan, Puerto Rico. Dec. 13, 2004.

Adinoff B, Williams MJ, Best SE, Zielinski T, Harris TS, Schreffler ER, Devous MD Sr. "Cholinergic receptor systems in cocaine-addicted subjects: Alterations regional cerebral blood flow." American College of Neuropsychopharmacology, 44th Annual Meeting. Waikoloa, Hawaii. Dec. 12, 2005.

Adinoff B. "HPA Axis Dysregulation in Alcoholism and the Clinical Trials Network: Texas Node." Texas Research Society on Alcoholism, 16th Annual Scientific Meeting. Texas A&M University System HSC, College Station, Tx. February 16, 2006.

Schreffler E, Adinoff B, Briggs R, Goyal A, Coleman A, Cheshkov S, Modhia S, Harris T, Devous MD Sr. "Stress, the HPA axis, and fMRI in alcoholism: Preliminary studies." Texas Research Society on Alcoholism, Texas A&M University, College Station, TX. February 17, 2006.

Adinoff, B, Williams MJ, Best SE, Zieklinski T, Harris T, Schreffler E, Devous MD. "Cholinergic receptor systems in cocaine-addicted subjects: Alterations in regional cerebral blood flow." 68th Annual Scientific Meeting of the College on Problems of Drug Dependence. Phoenix, AZ. June 18, 2006.

Williams MJ, Chandler PA, Best SE, Ye W, Brown MD, Adinoff B. "Dissection of hypothalamic-pituitary-adrenal axis pathology in 1-month-abstinent alcohol-dependent women: adrenocortical and pituitary glucocorticoid responsiveness." 29th Annual Meeting of the Research Society on Alcoholism. Baltimore, MD. June 26, 2006

Field CA, Duncan J, Washington K, Adinoff B. "Association of baseline characteristics and motivation

to change among patients seeking treatment for substance dependence." Texas Research Society on Alcoholism 17th Annual Scientific Meeting. Dallas, TX. March 16, 2007.

Adinoff B, Williams MJ, Best SE, Zielinski T, Harris TS, Schreffler ER, Devous MD. "Central probes of cholinergic receptor systems and associated cognitive functioning in cocaine-addicted subjects." College on Problems of Drug Dependence 69th Annual Scientific Meeting. Quebec, Canada. June 19, 2007.

Rosvall T, Adinoff B, Rilling LM, Cullum CM, Williams, MJ. "Comparison of three set shifting measures in cocaine-dependent males." College on Problems of Drug Dependence, Quebec City, Canada. June 2007.

Field CA, Duncan J, Washington K, Adinoff B. "Association of baseline characteristics and motivation to change among patients seeking treatment for substance dependence." College on Problems of Drug Dependence, Quebec City, Canada. June 2007.

Adinoff B, Devous MD Sr, Williams MJ, Best SE, Zielinski T, Harris TS. Central probes of cholinergic receptor systems and associated cognitive functioning in cocaine-addicted subjects. American College of Neuropsychopharmacology, 46th Annual Meeting. Boca Raton, Florida. Dec. 10, 2007.

Tirado CF, Maxwell JC. Adinoff B. The intranasal heroin epidemic among Latino adolescents in Texas: They're calling it "Cheese." San Juan, Puerto Rico. June 17, 2008.

Denton WH, Nakonezny PA, Adinoff B, Carroll KM. Relational discord at conclusion of treatment predicts future substance use for partnered patients. College on Problems of Drug Dependence, San Juan, Puerto Rico. June 18, 2008.

Field CA, Adinoff B, Harris TR, Ball SA, Carroll KM. Construct and predictive validity of the URICA. College on Problems of Drug Dependence, San Juan, Puerto Rico. June 18, 2008.

Adinoff B, Devous MD, Cooper DC, Best SE, Harris TS, Williams MJ. Increased neural response to lidocaine relative to procaine in healthy subjects. American College of Neuropsychopharmacology, 47th Annual Meeting. Scottsdale, AZ. Dec. 10, 2008.

Brown ES, Carmody SB, Schmitz JM, Caetano R, Adinoff B, Swann AC, Rush AJ. A randomized, double-blind, placebo-controlled trial of naltrexone in patients with bipolar disorder and alcohol dependence. American College of Neuropsychopharmacology, 47th Annual Meeting. Scottsdale, AZ. Dec. 10, 2008.

Mazzarulli A, Minhajuddin A, Harris H, Devous MD, Adinoff B. Relationship of impulsiveness to resting orbitofrontal cortex blood flow in cocaine-addicted and healthy subjects. American College of Neuropsychopharmacology, 47th Annual Meeting. Scottsdale, AZ. Dec. 11, 2008.

Denton W, Minhajuddin A, Nakonezny P, Adinoff B. Differential impact of alcohol dependence on families compared to other substances. Research Society on Alcoholism, 32nd Annual Meeting. San Diego, CA. June 2009.

Adinoff B, Devous MD Sr, Cooper DC, Best SE, Harris TS, Williams MJ. Increased neural response to lidocaine relative to procaine in healthy subjects. College on Problems of Drug Dependence. Revo, NV. June 23, 2009.

Kozel AF, Huang H, Adinoff B, Laken SJ, McClintock S, Husain M, Mapes KS, Bobb D, Tamminga C, Rush AJ, George M, Cullum M Briggs R, Trivedi T. Neural correlates of successful inhibition in late life depression. American College of Neuropsychopharmacology 48th Annual Meeting. Hollywood, FL. Dec 8, 2009

Yang HY, Yadav HC, Goyal AI, Devous MD, Briggs R, Adinoff B. Brain activation elicited by anticipatory anxiety in abstinent alcohol-dependent subjects. Research Society on Alcoholism, 33nd Annual Meeting. San Antonio, CA. June 2010.

Fielding SK, Shalvoy AM, Leachman LL, Minhajuddin A, Walker NR, North CS, Rao U, Xiao H, Adinoff B. Childhood trauma as a predictor of adult psychosocial stress in alcohol-dependent men. Research Society on Alcoholism, 33nd Annual Meeting. San Antonio, CA. June 2010.

Meng Y, Rao U, Xiao H, North CS, Adinoff B. Neuropeptide Y (NPY) and Brain-Derived Neurotrophic Factor (BDNF) responsivity after acute stress in alcohol-dependent and control subjects. Research Society on Alcoholism, 33nd Annual Meeting. San Antonio, CA. June 2010.

Leachman LL, Fielding SK, Shalvoy AM, Walker NR, Minhajuddin A, North CS, Rao U, Xiao H, Adinoff B. Relationship of self-reported childhood trauma to personality characteristics in alcohol-dependent men. Research Society on Alcoholism, 33nd Annual Meeting. San Antonio, CA. June 2010.

Shalvoy AM, LL Leachman, Fielding SK, Walker NR, Minhajuddin A, North CS, Rao U, Xiao H, Adinoff B. Antisocial personality characteristics and alcohol use as a predictor for cortisol reactivity to a behavioral stressor. Research Society on Alcoholism, 33nd Annual Meeting. San Antonio, CA. June 2010.

Braud J, Devous MD, Harris TS, Adinoff B. Relationship of impulsive personality traits and orbitofrontal rCBF in cocaine-addicted and healthy control subjects. College on Problems of Drug Dependence. Scottsdale, AZ. June 13, 2010.

Adinoff B, Harrington CR, Beswick TC, Graves M, Jacobs HT, Devous MD, Harris TS. Increased striatal activation in compulsive indoor tanners upon exposure to ultraviolet light compared to sham light. College on Problems of Drug Dependence. Scottsdale, AZ. June 17, 2010.

Adinoff B, Harrington C, Devous M, Jacobe H, Harris T. Increased striatal activation in compulsive indoor tanners upon exposure to ultraviolet light compared to sham light. American College of Neuropsychopharmacology. Miami, FL. December 7, 2010.

Liu P, Uh J, Devous MD, Adinoff B, Lu H. SPECT validation of pseudo-continuous arterial spin labeling MRI. International Society for Magnetic Resonance in Medicine, 19th Annual Meeting. Montreal, Canada. May 2011.

Denton WH, Winhusen T, Walker NR, Adinoff BH. Family discord is associated with increased substance use for pregnant substance users. International Association for Relationship Research Mini-Conference on Health, Emotions, and Relationships. Tucson, AZ. October 2011.

Braud J, Harris TS, Devous MD, Spence JS, Briggs R, Walker NR, Cullum M, Adinoff B. Neural alterations during decision-making in cocaine-addicted subjects. Metroplex Days. Dallas, TX. February 2012.

Adinoff B. Neuroimaging in addiction: Common threads. Texas Research Society on Alcoholism, 22nd Annual Scientific Meeting. Texas A&M University System HSC, College Station, TX. February 24, 2012.

Winhusen T, Lewis D, Adinoff B, Brigham G, Kropp F, Donovan D, Somoza E. Failure to look before leaping: The Barratt Impulsiveness Scale predicts treatment completion in cocaine-and methamphetamine-dependent patients. College on Problems of Drug Dependence. Palm Springs, CA. June 11, 2012.

Mete M, Adinoff B, Devous MD, Spence JS. A machine learning approach for patient classification in cocaine addiction via SPECT images. College on Problems of Drug Dependence. Palm Springs, CA. June 11, 2012.

Adinoff B, Devous MD, Williams MJ, Harris TS, Best SE, Dong H, Zielinski TA. Differences in regional cerebral blood flow response to a 5HT3 antagonist in early-and late-onset cocaine dependence. College on Problems of Drug Dependence. Palm Springs, CA. June 14, 2012.

McHugh M, Gu H, Yang Y, Braud J, Devous M, Briggs R, Walker NR, Adinoff B, Stein E. Resting state network dynamics predict relapse in cocaine-dependent individuals. American College on Neuropsychopharmacology 51st Annual Meeting. Hollywood, FL. December 4, 2012.

Gu H, McHugh M, Yang Y, Shope C, Braud J, Devous M, Briggs R, Walker NR, Cullum M, Stein E, Adinoff B. Resting regional cerebral blood flow to predict relapse in cocaine dependent individuals. American College on Neuropsychopharmacology 51st Annual Meeting. Hollywood, FL. December 4, 2012.

Liu P, Adinoff B, Tamminga CA, Filbey F, Lu H. Impact of cocaine use on brain metabolism: Hypoactivity, dose dependence, and relationship to cognitive ability. Proceedings of the 21st Annual Meeting of ISMRM, Salt Lake City, Utah, USA. April 25, 2013. p.738.

Merrick C, Adinoff B, Gu H, McHugh M, Devous MD, Briggs R, Sunderajan P, Yang Y, Stein EA. Localized functionally connected neural predictors of relapse in cocaine dependence. Texas Research Society on Alcoholism 37th Annual Meeting. San Antonio, TX. February 21, 2014.

Merrick C, Adinoff B, Gu H, McHugh M, Devous MD, Briggs R, Sunderajan P, Yang Y, Stein EA. Localized functionally connected neural predictors of relapse in cocaine dependence. Behavior, Biology and Chemistry. San Antonio, TX. March 14-16, 2014.

Vingren JL, Adinoff B, Duplanty AA, Budnar RG, Luk HY, Xiao H, Hill DW. Muscle glucocorticoid receptors and long-term alcohol abuse: Preliminary findings. 13th Biennial Advances in Skeletal Muscle Biology in Health and Disease Conference, Gainesville, Florida. March 2014.

Akgun D, Sakoglu M, Mete M, Esquivel J, Adinoff B. GPU-accelerated dynamic functional connectivity analysis for functional MRI data using open CL. IEEE International Conference. Milwaukee, WI. June 2014.

Adinoff B, Gu H, Merrick C, McHugh M, Devous M, Yang Y, Stein E. Localized and functionally connected neural predictors of relapse in cocaine dependence. College on Problems of Drug Dependence. San Juan, Puerto Rico. June 18, 2014.

Price JL, Leonard D, Rao U, Walker R, Javors M, Xiao H, Adinoff B (2014). Ongoing stress moderates pituitary-adrenal reactivity in predicting post-treatment drinking severity. Poster presented at the 37th Annual Meeting of the Research Society of Alcoholism (RSA), Bellevue, WA (June 21-25, 2014) and Behavior, Biology, and Chemistry, San Antonio, TX (March 14-16, 2014).

Adinoff B, Aubert PM, Harris TS, Filbey FM, Devous MD, Price JL, Jacobe HM, Seibyl J. Dopamine efflux in response to ultraviolet radiation in addicted sunbed users. American College on Neuropsychopharmacology 53rd Annual Conference. Phoenix, AZ. Dec 9, 2014.

Rice J, Spence J, Rubia K, Harris TS, Briggs R, Devous M, Adinoff B. The anterior salience network and impulsivity in cocaine-dependent individuals. 12th Annual AMA Research Symposium-Medical Student Section. Dallas, TX. November 7, 2014.

Wilcox CE, Ling JM, Pommy JM, Adinoff B, Bigelow RC, Mayer AR, Bogenschultz MP. Prazosin decreases striatal bold response to conditioned stress stimulus in alcohol use disorder. Research Society on Alcoholism. San Antonio, TX. June 23, 2015.

Adinoff B, Spence J, Gu H, Rice J, Rubia K, Yang Y, Briggs R, Walker R, Stein EA. Disrupted relationship of conscientiousness to BOLD activation during error monitoring and resting state functional connectivity in cocaine-dependent and healthy control subjects. *American College on Neuropsychopharmacology 54th Annual Conference.* Hollywood, FL. Dec. 8, 2015

Sparks H, Morrow L, Javors, M, Adinoff B. Dexamethasone suppressed neurosteroid predicts post-treatment drinking in alcohol-dependent men. Texas Research Society on Alcoholism, Dallas, TX. February 19, 2016.

Kepinski I, Gu H, Blackledge S, Yang Y, Stein EA, Adinoff B. Amygdala and NEO impulsiveness (N5) in cocaine use disorders. Texas Research Society on Alcoholism, Dallas, TX. February 19, 2016.

Blackledge S, Kepinski I, Yang H, Adinoff B. Effects of neuroticism and alcohol dependence on neuronal reactivity during uncertain heat threat: Implications for the default mode and executive control networks. Texas Research Society on Alcoholism, Dallas, TX. February 19, 2016.

Wright R, Adinoff B. Bupropion misuse: A systematic review. UT Southwestern Medical Center. May 25, 2016

Adinoff B, Blackledge S, Kepinski I, Gu H, Yang Y, Stein EA. Amygdala volume, resting state functional connectivity, and NEO Impulsiveness (N5) in cocaine use disorder. American College on Neuropsychopharmacology 55th Annual Conference. Hollywood, CA. Dec. 6, 2016.

Becker JE., Price JL, Kandil E, Shaw MA, Suris A, Kroener S, Brown ES, Adinoff B. Efficacy of lidocaine in disrupting cocaine-cue induced memory reconsolidation. Behavior, Biology, and

Chemistry: Translational Research in Addiction Conference, San Antonio, TX. March 4, 2017

Price JL, Acevedo S, Javors MA, Walker R, Nixon SJ, Adinoff B. CRHR1 genotype differentially moderates HPA axis in healthy controls and alcohol-dependent men. 40th Annual Meeting of the Research Society on Alcoholism (RSA), Denver, CO. June 24-28, 2017.

Price JL**,** Frazier IR, Javors MA, Walker R, Nixon SJ, Adinoff B. Differences in HPA function between Black and White alcohol-dependent men. Poster presented at the University of Florida College of Medicine Celebration of Research, Gainesville, FL (February 27, 2017), the 4th Annual International Congress on Alcoholism and Stress, Volterra, Italy (May 9-12, 2017), and the 40th Annual Meeting of the Research Society on Alcoholism (RSA), Denver, CO (June 24-28, 2017). *Finalist for the Enoch Gordis Research Award.*

Westover A, Adinoff B, Halm E, Nakonezny P. Risk of stimulant use disorder and mortality among incident users in the Veterans Administration. College on Problems in Drug Dependence 79th Annual Scientific Conference. Montreal, Canada. June 22, 2017.

Yu J-C, Fiore VF, Spence JS, Briggs RW, Braud J, Adinoff B, Gu X. Multiple system dysfunction in addiction: evidence from model-based fMRI. 47th annual meeting of Society for Neuroscience, Washington, DC. November, 2017.

Sakoglu U, De Leon J, Huerta C, Galla M, M Mutlu, Adinoff B. Classification of cocaine addiction using Hilbert-Curve Ordering of fMRI activations. International Society for Magnetic Resonance in Medicine (ISMRM) Workshop on Machine Learning. Pacific Grove, CA. March 14-18, 2018.

Becker JE, Price JL, David Leonard D, Suris A, Kandil E, Meredith Shaw M, Sven Kroener S, Brown ES, Adinoff B. The Efficacy of Lidocaine in Disrupting Cocaine Cue-Induced Memory Reconsolidation." CPDD 80th Annual Scientific Meeting, San Diego, CA. June 14, 2018.

Community Presentations:

"The Neurobiology of Drug and Alcohol Addiction." In *Mitigation – How to Explain Behavior,* The Center for American and International Law. Plano, TX. April 30, 2005.

"What We're Learning About the Neuroscience of Addiction". *Reinvesting in Justice: What Comes Next?* Center for Court Innovation. Dallas, TX. November 12, 2015.

Speaker, Panel on "Cops, Docs, and Clergy- War on Drugs Program." Republican Liberty Caucus of Texas Convention. Austin, TX. February 12, 2016.

Speaker, Panel on "Cops, Docs, and Clergy- War on Drugs Program." Huston-Tillotson University. Austin, TX. February 12, 2016.

Speaker, Panel on Medical Marijuana, *Pro Athletes Pro Cannabis*, Ft. Worth, TX. April 21, 2017.

Speaker, Panel on "Cannabis and Chronic Traumatic Encephalopathy," *Southwest Cannabis Conference and Expo*, Ft. Worth, TX. April 22, 2017.

Speaker, Veterans Cannabis Forum, American Legion Post 453, Dallas, TX. May 26, 2018

Speaker, Panel on "Medical Cannabis: What does the research tell us?" *Texas Marijuana Policy Conference,* Austin, TX. August 11, 2018.

Speaker, Panel on "PTSD, Pain and Cannabis." *Online Texas Veteran Cannabis Conference*. Oct 17, 2020.

Speaker, Panel on "Texas Veterans: Service-Related Injuries and Cannabis Treatment*." Texas Marijuana Policy Conference 2020* (Virtual). Nov 11, 2020.

Speaker, Panel on "Remembering the Patients." *Yes We Cannabis Rhode Island*. Facebook Live Stream. March 14, 2022.

Speaker, Panel on "Brittney Griner's Imprisonment in the Context of Cannabis Prohibition in the US & Russia." Doctors for Cannabis Regulation webinar. Sept 14, 2022.

Speaker, Panel on "Understanding the medical science behind substance misuse, addiction, and recovery." Denver City Council. Denver, CO. Feb 1, 2023.

Interview (virtual), VAC Roundtable #51. Veterans Action Council. Feb 3, 2023.

Speaker, Panel on “Cannabis Law Reform Leading the Way Towards More Effective Drug Control and the Attainment of the [UN] Sustainable Development Goals.” Chair: Myrtle Clark. UN Commission on Narcotic Drugs (CND) #66. Vienna, Austria. March 15, 2023.

Podcasts

- Psychedelic Science 2023: Doctors for Cannabis Regulation. Cannabis Radio.com. July 11, 2023
- Psychedelica Lex with Gary Smith (Part 1, 2, 3). Nov 27, 2020
  - Part 1
  - Part 2
  - Part 3

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Fax: 609-688-0401

PLACE OF BIRTH

Philadelphia, Pennsylvania

EDUCATION

1994	MD, University of Pennsylvania School of Medicine, Philadelphia, PA
1990	AB in biology, *magna cum laude*, Princeton University, Princeton, NJ

POSTGRADUATE TRAINING

1994-1998	Resident, Psychiatry, McLean Hospital, Harvard Medical School, Belmont, MA

ACADEMIC APPOINTMENTS

2010-	*Clinical Associate Professor*, Department of Psychiatry, Rutgers Robert Wood Johnson Medical School (**RWJMS**), Piscataway, NJ
2000-2010	*Clinical Assistant Professor*, Department of Psychiatry, RWJMS, Piscataway, NJ
2000-	*Community Fellow*, Mathey College, Princeton University, Princeton, NJ
1999-2000	*Clinical Instructor*, Department of Psychiatry, RWJMS, Piscataway, NJ
1994-1998	*Clinical Fellow*, Psychiatry, Harvard Medical School, Boston, MA

HOSPITAL APPOINTMENTS

2008-	*Chairman*, Continuing Medical Education Committee, Penn Medicine Princeton Health (**PMPH**, formerly Princeton HealthCare System [**PHCS**]), Princeton, NJ
2022-	*Senior Attending Staff*, PMPH, Princeton, NJ
2000-2022	*Active/Attending Staff*, PMPH, Princeton, NJ
1998-2000	*Associate Staff*, PHCS, Princeton, NJ
1998-1999	*Courtesy Attending Staff*, Carrier Foundation, Belle Mead, NJ

EMPLOYMENT HISTORY

2018-2020	*Chief Medical Advisor*, 4Front Ventures. Provided information and guidance on evidence-based cannabis science and medicine to company leadership and employees at a multistate cannabis cultivator and retailer. Wrote educational materials for physicians, patients, staff and

	the public. Identified and recruited experts in the scientific community and wrote and edited content for state license applications.
2016-	*Consultant*, Princeton Psychiatry and Consulting, LLC, Princeton, NJ. Serve as an expert medical consultant on drug policy-related topics for government, businesses, investors, education companies and policy groups. Speak at cannabis-related conferences and other events. Design cannabis labeling and packaging. Assist with regulatory compliance and medical issues with completion of state license applications.
2008-	*Director of Continuing Medical Education*, PMPH (formerly PHCS), Princeton, NJ. Provide all leadership and supervision in connection with the offering, communication and management of educational programs to physicians on the PMPH Medical Staff, while meeting all guidelines and standards of the Accreditation Council for Continuing Medical Education and the American Medical Association.
1999-	*Director of Professional Education*, Department of Psychiatry, PMPH (formerly PHCS), Princeton, NJ. Organize grand rounds and moderate case conferences for psychiatrists, psychologists, nurses and social workers.
1998-	*Private Practice Psychiatrist*. Princeton Psychiatry and Consulting, LLC, Princeton, NJ. Provide outpatient psychiatric care to adults in the community, using the modalities of psychotherapy and psychopharmacology.
1998-1999	*Consult-Liaison Psychiatrist*, The Medical Center at Princeton, Princeton, NJ. Completed all routine psychiatric consultations on medical and surgical floors. Served as liaison to medical and nursing staff.
1998-1999	*Evaluating Psychiatrist*, Princeton House Behavioral Health, Princeton, NJ. Assessed and monitored patients in the geriatric, substance abuse and general adult partial hospital programs of Princeton House.

LICENSURE AND CERTIFICATION

1999-	American Board of Psychiatry and Neurology – Board Certification in Psychiatry
2022-	Pennsylvania Board of Registration in Medicine – inactive license
2016-2022	Pennsylvania Board of Registration in Medicine – active license
1998-	New Jersey State Board of Medical Examiners – full license
1996-1998	Massachusetts Board of Registration in Medicine – full license
1992-1995	United States Medical Licensing Examination – Steps 1, 2 and 3

AWARDS AND HONORS

2022	NJ.com: 22 People and Places to watch in the NJ Cannabis Space in 2022
2021	Insider NJ: Top 100 influential voices in the cannabis debate (insidernj.com)
2021	NJ.com: 21 People and Places to watch in the NJ Cannabis Space in 2021
2019	Insider NJ: Top 100 influential voices in the cannabis debate (insidernj.com)
2018	Honorary Board of ICANNA: International Institute for Cannabinoids, Slovenia
2012	Distinguished Fellow of the American Psychiatric Association (DFAPA)
2010	Fellow of the American Psychiatric Association (FAPA)
2007	Odesser Award for Outstanding Contribution to Judaic Numismatics and Exonumia
1990	High honors in biology, Princeton University

1990 Sigma Xi Science Honor Society, selected by members of Princeton's faculty
1990 Charles M. Cannon Memorial Prize for best thesis presentation, Princeton University Department of Biology

PROFESSIONAL SOCIETIES AND PATIENT ADVOCACY GROUPS

2023- *Co-founder and Past President*, Doctors for Drug Policy Reform (D4DPR)
2021-2023 *Founder and Past President*, Doctors for Cannabis Regulation (DFCR)
2021- *Founding board member*, NJ-NORML
2015-2021 *Founder and Board President*, Doctors for Cannabis Regulation (DFCR)
2014- *Founding steering committee member*, New Jersey United for Marijuana Reform
2012- *Distinguished Fellow*, American Psychiatric Association (APA)
2008- *Member*, Medical Society of New Jersey (MSNJ)
2003- *Physician Advisor*, New Jersey State Chapter of the Depression and Bipolar Support Alliance (DBSA-NJ)
1998- *Professional Member*, National Alliance for the Mentally Ill (NAMI)
1998- *Member*, New Jersey Psychiatric Association (NJPA)
2020 *Steering committee member*, NJ CAN 2020, a cannabis legalization campaign
2010-2012 *Fellow*, APA
1994-2010 *General Member*, APA
1994-1998 *Member*, Massachusetts Psychiatric Society (MPS)

SELF REPORT OF TEACHING

2008- *Director of Continuing Medical Education*, Penn Medicine Princeton Health, Princeton, NJ. Provide leadership and supervision in connection with the offering, communication and management of educational programs to physicians on the PMPH Medical Staff, while meeting all guidelines and standards of the Accreditation Council for Continuing Medical Education and the American Medical Association.
2004- *Director of Professional Education*, Department of Psychiatry, Penn Medicine Princeton Health. Organize grand rounds and moderate case conferences for psychiatrists, nurses and social workers. Supervise a second monthly grand rounds run by a psychologist.
2003-2005 *Member*, Medical Advisory Board of the Princeton Fitness & Wellness Center.
1999-2004 *CME Course Director for Psychiatry*, Department of Psychiatry, Medical Center at Princeton. Organized grand rounds for the department of psychiatry and created a case conference for psychiatrists.
1999-2008 *Member*, CME Committee, Princeton HealthCare System.
2007-2012 *Member*, Ethics Consultation Subcommittee of the Biomedical Ethics Committee, Princeton HealthCare System.
1999-2012 *Member*, Biomedical Ethics Committee, Princeton HealthCare System.
1998-1999 *Clinical Instructor*, The Medical Center at Princeton, Robert Wood Johnson Medical School. Teaching third and fourth year medical students completing their psychiatry rotations on the Consult-Liaison Service at the Medical Center at Princeton.

1997-1998 *Chief Resident*, Bipolar and Psychotic Disorders Program, McLean Hospital. Supervised sixteen second year residents from the MGH/McLean Residency Program. Organized weekly case conferences with visiting consultants on the inpatient unit. Created and organized weekly outpatient clinic for four third year residents, including monthly case conferences.

1997-1998 *Preceptor*, Core Clerkship in Psychiatry, Harvard Medical School. Supervised third and fourth year medical students completing their psychiatry rotations at McLean Hospital.

1995-1998 *Tutor*, Psychopathology & Introduction to Clinical Psychiatry, Harvard Medical School. Semester-long course for second year medical students to learn about psychiatric interviewing and the mental status examination.

1993-1994 *Coordinator*, 1994 Penn Med Ed Software Project, University of Pennsylvania School of Medicine. Conceived and facilitated work on programs in human development, embryology and endocrine physiology by medical students and faculty.

1992-1993 *Founder and coordinator*, 1993 Penn Med Ed Software Project, University of Pennsylvania School of Medicine. Selected and supervised eight medical students to complete five computer programs.

1991-1992 Conceived and designed *Histological Anatomy Review Program*; selected and supervised eight medical students' completion of this and *Gross Anatomy Review Program.*

1992 *Exhibitor*, Symposium: *Computers in Health Care Education*, Health Sciences Library Consortium & Thomas Jefferson University, Philadelphia, PA.

1992 *Exhibitor*, Symposium: *Computers in Medical Education*, University of Pennsylvania, Philadelphia, PA.

1991 Conceived, designed and illustrated *Gross Anatomy Review Program*, an animated computer dissection and tutorial.

SELECTED PUBLICATIONS

Editorial Boards:

2021- *Member*, Editorial Board, *Medical Cannabinoid Journal*
2020- *Member*, Editorial Board, *Cannabis Science and Technology*
2019-2023 *Member*, Editorial Board, *American Journal of Endocannabinoid Medicine*

Journal Articles:

Nathan, D.L., Oepen, G., Havens, L. and McClung, E.D. "Two Views of a Delusion." *Harvard Rev Psychiatry* 1998; 6: 97-104.

Nathan, D.L. "A 'New' Proto-Cuneiform Tablet." *Cuneiform Digital Library Bulletin* 2003:4. March 2003.

Nathan, D.L. Review of *The Midnight Disease*. *American Journal of Psychiatry*. October 2004; 161: 1937-1938.

Nathan, D.L. "A Hebrew Letter on the New World's First Coins?" *The Shekel*. January-February 2006.

Nathan, D.L. and Crafton, D. "The Making and Remaking of *Gertie*." *Animation* 8:1. March 2013. pp. 23-46.

Nathan, D.L. "That summer evening, long ago, a-sitting on a gate." *The Knight Letter.* January 2014. pp. 23-26.

Nathan, D.L., Elders, J., Clark, H.W. "The Physicians' Case for Marijuana Legalization." *American Journal of Public Health* 107:11. November 2017. pp. 1746-1747.

Nathan, D.L. "Setting the Standard for Cannabis Labeling: Introducing the Universal Cannabis Product Symbol and the Universal Cannabis Information Label." *Cannabis Science and Technology* 3:6, August 2020. Pp. 44-52.

Nathan, D.L. and Nathan, E. "Why All Legalized U.S. Jurisdictions Should (and Probably Will) Adopt the International Intoxicating Cannabis Product Symbol (IICPS)." *Cannabis Science and Technology* 5:1, November 2021.

Nathan, D.L. "Creating a Symbol of Best Practices in Cannabis Regulatory Standards." *Cannabis & Tech Today* 5:3, March 2024.

News/Magazine Articles and Interviews:

"Find ways to work through those holiday or winter blues." *Princeton Packet*. December 18, 1998. p. 23A.

"Depression Guide: You're Not Alone." *Barron's*. September 3, 2001. pp. 34-35.

"Try to remember the kind of September..." *Princeton Packet*. September 21, 2001.

"Shedding Light -- And Darkness." *Barron's*. March 4, 2002.

"Trouble at the Office." *Barron's*. September 4, 2006. p. 36.

"This is Your Brain on Money." *Barron's*. September 3, 2007. p. 40.

"A Doctor's Case for Legal Pot." *Wall Street Journal*. January 15, 2010. p. 21.

"Matter Over Mind: Psychiatrists and their Pills." *Barron's*. July 5, 2010. p. 33.

"Is It High Time? Fresh looks at marijuana." *Barron's*. March 7, 2011. pp. 30-31.

"Why Marijuana Should Be Legal for Adults." *CNN.com*. January 9, 2013. Featured Op-Ed.

"Calls to Legalize Pot Are Gaining America's Support." *CNN.com.* January 16, 2013. Featured Op-Ed.

"How to Regulate Pot When It's Legal." *CNN.com.* August 26, 2013. Featured Op-Ed.

"Fighting Marijuana… Or Reality?" *CNN.com.* September 11, 2013. Featured Op-Ed.

"Where It All Began: Research sparks quest to find Princeton's Unknown Player." Princeton Alumni Weekly. October 22, 2014. p. 15.

Dozens of articles and interviews since 2015 on cannabis legalization and general drug policy reform in a variety of media outlets, including CNN*, The New York Times, ESPN, Washington Post, Denver Post, San Francisco Chronicle, Las Vegas Review-Journal, Providence Journal, The Guardian, Huffington Post, MedPage Today, MD Magazine, Leafly, The Cannabist,* NBC 4 New York, NBC 3 Las Vegas, CBS 3 Philadelphia, Fox 29 Philadelphia, NJTV News, WKXW 101.5 FM Trenton, KFNX 1100 AM Phoenix, WIP 1210 AM Philadelphia and other outlets.

Books and Other Monographs:

Web Repair in Several Species of Orb Weaving Spiders [Senior Thesis]. Princeton, NJ: Princeton University, 1990. 67 pp.

The Book of Nathan: Memoirs of a Nineteenth Century Romanian Immigrant. Princeton, NJ, 2006. 128 pp.

Medical Education Software:

Creator, Designer and Illustrator, *Gross Anatomy Review Program*, a computerized dissection, atlas, review, and self-test, University of Pennsylvania School of Medicine, 1991-3.

Creator and Designer, *Histological Anatomy Review Program*, a computerized atlas, review, and self-test, University of Pennsylvania School of Medicine, 1992-3.

Creator, Designer and Animator, *Basic Embryology Review Program*, an animated atlas and review of prenatal development, University of Pennsylvania School of Medicine, 1994.

Creator and Designer, *Human Development Along a Continuum,* a review of human psychological and physiological development along a continuum, University of Pennsylvania School of Medicine, 1994.

Creator and Designer, *Advanced Teaching Tool for Introductory Endocrinology*, a review of endocrinological physiology, pathology, and pathophysiology, University of Pennsylvania School of Medicine, 1994.

Film/Theater:

Executive Producer, *Gertie*, a reconstruction of Winsor McCay's 1914 vaudeville stage performance and restoration of his animated film. Creator and animator for the Gertie Project beginning in 2003, and one of three scholars who served as executive producers. World premiere at the Annecy Film Festival, France, June 16, 2018.

Other Publications:

Graphics Editor, *American Journal of Ethics and Medicine*, 1990-1991.

Theme Editor, *Scope*, the University of Pennsylvania School of Medicine's Annual, 1994.

Editor, *Poor David's Almanac for the Year 2006*, application for the Palm OS, December 2005.

Editor, *Poor David's Almanac for the Year 2007*, application for the Palm OS, December 2006.

Editor, *Poor David's Almanac for the Year 2008*, application for the Palm OS, December 2007.

SELECTED PRESENTATIONS

Lectures and Seminars:

"Management of Psychosis." Lecture to residents, Robert Wood Johnson Medical School, December 17, 1998.

"Update on Antidepressants." Grand Rounds, Department of Medicine, Medical Center at Princeton, February 2, 1999.

"Two Views of a Delusion." Paper Presentation, I Department of Psychiatry, Medical University of Warsaw, Poland, July 6, 1999.

"Management of the Paranoid Patient." Lecture to residents, Robert Wood Johnson Medical School, October 14, 1999.

"Psychiatric Emergencies." Lecture to residents, Medical Center at Princeton, August 25, 1999/July 25, 2001.

"Acute Psychosis." Lecture to residents, Medical Center at Princeton, Several years since July 12, 2000.

"Trauma and Psychiatry after September 11th." Lecture to faculty fellows at Princeton University, November 28, 2001.

"Ask the Doctor." Seminars with members of DBSA New Jersey, periodically since 2003.

"Alcoholism." Lecture to residents, Medical Center at Princeton, February 5, 2003.

"Origins of Animation." Lecture to faculty fellows at Princeton University, February 25, 2003.

"Depression in Adults." Grand Rounds, Department of Medicine, University Medical Center at Princeton, June 15, 2004.

"Introduction to Psychiatry." Lecture to public at Princeton Fitness and Wellness Center, November 15, 2004.

"Meteorites: Science or Cosmic Vandalism?" Lecture to faculty fellows at Princeton University, February 9, 2005.

"A Psychiatrist's Perspective on Depression." Lecture at symposium *Mental Illness as a Spiritual Journey*. Princeton Theological Seminary, April 18, 2006.

"America's History in Coins." Lecture to faculty fellows at Princeton University, October 17, 2006.

"Art and Science of Psychiatric Diagnosis."

1. Grand Rounds, Department of Psychiatry, UMDNJ Camden, October 30, 2007.
2. Lecture to Princeton Independent Consultants at Nassau Club, October 20, 2008.
3. Grand Rounds, Department of Psychiatry, Princeton House, January 14, 2009.
4. Lecture to faculty fellows at Princeton University, April 22, 2009.
5. Keynote Address at DBSA NJ Annual Conference, May 8, 2010.
6. Grand Rounds, Department of Medicine, University Medical Center at Princeton, December 14, 2010.

"Cannabis." Lecture to faculty fellows at Princeton University, November 17, 2010.

"New Directions New Jersey: A Public Safety and Health Approach to Drug Policy." Panel Discussion for Drug Policy Alliance, March 19, 2011.

"2011 Update on Psychiatric Medications." Lecture to lay public at NAMI Mercer Harvest of Hope Conference, October 1, 2011.

"2011 Update on Psychotropics." Grand Rounds, Department of Medicine, University Medical Center at Princeton, February 21, 2012.

"2012 Update on Psychiatric Medications." Lecture to lay public at NAMI Mercer Harvest of Hope Conference, October 6, 2012.

"Ethics, Medicine, and Mental Health Treatment." Lecture, Princeton Theological Seminary, October 8, 2012.

"Bill to Tax and Regulate Marijuana Like Alcohol." Press Conference, Pennsylvania State Capitol, February 11, 2013.

"Marijuana and Legalization: What Clinicians Need to Know." Grand Rounds, Department of Psychiatry, Princeton House, April 8, 2013.

"2013 Update on Psychiatric Medications." Lecture to lay public at NAMI Mercer Harvest of Hope Conference, October 5, 2013.

"Marijuana and Legalization: What Clinicians Need to Know." Grand Rounds at McCosh Infirmary, Princeton University. November 5, 2013.

"So You're Thinking about Medical School." Lecture to Princeton University pre-meds. November 6, 2013.

"Stressed or Sick: Distinguishing Psychiatric Disorders from Everyday Problems." Lecture to faculty fellows at Princeton University, November 20, 2013.

"A Doctor's Perspective on Marijuana Legalization." Lecture at Windrows, Plainsboro, NJ, March 5, 2014.

"Schizophrenia." Lecture to NAMI Mercer, April 15, 2014.

"Medications for Anxiety and Depression." Lecture to staff at Longyearbyen Sykehuset, Longyearbyen, Svalbard, August 21, 2014.

Dozens of lectures and seminars since 2015 on cannabis legalization and regulation in a variety of settings, including the International Drug Policy Reform Conference, Policy Committee of the Medical Society of New Jersey, CannMed 2017 at Harvard Medical School, Princeton University, Rider University symposium on cannabis policy, Rutgers University symposium on cannabis policy, Southwest Cannabis Conference, Cannabis Business Executives Conference and other venues.

<u>Testimony in State Legislatures</u>:

Testimony on marijuana legalization; Senate Judiciary Committee, **New Jersey State Legislature**, Trenton, NJ, November 16, 2015.

Testimony on An Act Concerning the Regulation and Taxation of the Retail Sale and Cultivation of Marijuana (HB 5314); Public Health Committee, **Connecticut General Assembly**, Hartford, CT, March 7, 2017.

Testimony on Cannabis Regulation, Control and Taxation Act (H 5555); House Judiciary Committee, State of **Rhode Island General Assembly**, Providence, RI, April 11, 2017.

Written testimony on the Delaware Marijuana Control Act (HB 110); House Revenue and Finance Committee, **Delaware General Assembly**, May 10, 2017.

Testimony on Cannabis Legalization Bill (S 2195); **New Jersey State Legislature**, Trenton, NJ, June 19, 2017.

Testimony on Cannabis Regulation and Taxation Act (SB 316, HB 2353); **Illinois General Assembly**, Chicago, IL, January 22, 2018.

Testimony on marijuana legalization; Oversight, Reform and Federal Relations Committee, **New Jersey State Legislature**, Trenton, NJ, March 5, 2018.

Testimony on the reclassification of marijuana; **New Jersey Division of Consumer Affairs**, Trenton, NJ, April 24, 2018.

Testimony on cannabis legalization; Joint Standing Committees on Codes, Health, Governmental Operations, and Alcoholism and Drug Abuse, **New York State Assembly**, New York, NY, October 16, 2018.

Testimony on An Act Relating to the Regulation of Cannabis (S 54); Senate Judiciary Committee, **Vermont General Assembly**, January 31, 2019.

Written Testimony on New Jersey Cannabis Regulatory and Expungement Aid Modernization Act (S 2703 / A 4497); Senate Judiciary Committee and Assembly Judiciary Committee, **New Jersey State Legislature**, Trenton, NJ, March 18, 2019.

Testimony on marijuana legalization, House Finance Committee; **Pennsylvania General Assembly,** Harrisburg, PA, June 10, 2019.

Testimony on An Act Relating to the Regulation of Cannabis (S 54); House Health Care Committee, **Vermont General Assembly**, January 24, 2020.

Written Testimony on An Act Concerning the Adult Use of Cannabis (SB 16); Judiciary Committee, **Connecticut General Assembly**, Hartford, CT, March 3, 2020.

Testimony on enabling legislation for marijuana legalization; Assembly Oversight, Reform and Federal Relations Committee, **New Jersey State Legislature**, Trenton, NJ, November 9, 2020.

Testimony on the New Jersey Cannabis Regulatory, Enforcement Assistance, and Marketplace Modernization Act (A21); Assembly Appropriations Committee, **New Jersey State Legislature**, Trenton, NJ, November 19, 2020.

Testimony on the prevention of non-medical underage cannabis use; Senate Judiciary Committee, **New Jersey State Legislature**, Trenton, NJ, February 15, 2021.

Testimony on cannabis legalization (HB 150); House Health & Human Development Committee, **Delaware General Assembly**, March 24, 2021.

Testimony on marijuana regulation (HB 305); House Health & Human Development Committee, **Delaware General Assembly**, January 26, 2022.

Testimony supporting cannabis labeling requirements (LD2147); Joint Standing Committee of Veterans and Legal Affairs, **Maine State Legislature**, January 24, 2024

Testimony on cannabis regulation (SB 3335, HD1); House Committee on Consumer Protection and Commerce, **Hawai'i State Legislature**, March 18-20, 2024.

Testimony in United States Congress:

Testimony on marijuana legalization, "Marijuana Laws in America: Racial Justice and the Need for Reform." Subcommittee on Crime, Terrorism and Homeland Security; US House Judiciary Committee. **United States House of Representatives**, Washington, DC, July 10, 2019.

Date Prepared: April 30, 2024

540-365-2141 - FROM THE DESK OF MICHAEL KRAWITZ -
EMAIL: MIGUET@INFIONLINE.NET

26 Sept 2024. I hereby give notice that I wish to present and argue my position during the upcoming Hearing by an Administrative Law Judge on cannabis rescheduling:

RE: Schedules of Controlled Substances: Rescheduling of Marijuana — Hearing on the Proposed Rule by the Drug Enforcement Administration

https://www.federalregister.gov/documents/2024/05/21/2024-11137/schedules-of-controlled-substances-rescheduling-of-marijuana

I am a disabled United States Air Force Veteran and I will be harmed by the proposed rule.

Michael Krawitz — Written Notice as interested party:

I have suffered injury from schedule #1 placement of cannabis and while schedule #3 rescheduling will resolve some of these issues I will still continue to suffer unnecessary harm and continued injury under the proposed schedule #3.

Schedule #3 is unacceptable given the totality of the evidence and experience we have from the many states' medical cannabis and adult recreational cannabis access programs as well as given the academic and scientific record.

State medicinal access programs and adult recreational access programs operate in a consensus fashion under state laws that more closely aligns with schedule #5 than schedule #3.

The Department of Veterans Affairs - Hospital System, given the fact that schedule #3 will require time consuming FDA approval before such medicines will be able to be dispensed from VA pharmacies, will not be able to integrate cannabis into Veterans pain management or Post Traumatic Stress treatment as they certainly would be able to under a schedule #5 placement or by de-scheduling.

Veterans Affairs hospitals, under schedule #3, will not be able to facilitate cannabis prescriptions until FDA approves new cannabis medicines. Such FDA approvals will be granted for products based upon the many preparations available in dispensaries operated under state laws. This process is onerous and it takes many years for FDA approval for a similar product that is already widely available from said dispensaries.

Schedule #5 placement will allow my VA doctor to prescribe / recommend my cannabis medication and for the Veterans Affairs Administration to pay for the product that I would then go purchase myself in much the same way that Veterans currently receive a clothing allowance and then buy their own clothes.

I suffer from multiple injuries I sustained during my military service and I have received care from VA hospitals. I previously participated in a factory trial of Marinol [FDA approved THC] and it caused side effects that were so terrible the trial had to be discontinued. I have used whole cannabis preparations from dispensaries in California, Oregon, Washington and Virginia stemming from a doctor's cannabis 'recommendation'. These cannabis products improved my quality of life by helping me to better manage

my pain. Current VA policy spells out how doctor's inside VA, because of schedule #1 placement of cannabis, cannot write a 'recommendation' for cannabis. This VA policy has made it necessary for me, a 100% total and permanent rated disabled Veteran to have to leave the VA and create a new doctor relationship outside the VA hospital system at my own expense. If cannabis is placed in schedule #3 my situation will be only partially repaired as I will then be able to, for the first time, have a VA doctor write my 'recommendation' for cannabis but will still have to pay for my medication out of pocket even though all of my other medications stemming from my service connected injuries are covered by the VA.

Schedule #5 is more appropriate - follow the experience not just the evidence and law: Given the experience in the 30+ states and territories enacting such laws since 1996 and the fact that medical boards, state legislatures, hospital systems, nurses associations, patients, their families, and their communities have carefully thought through the many access issues and have converged on a consensus policy supporting over the counter access that the DEA should instead reschedule to schedule #5 to reflect this reality.

It should be noted that connected to the 30,000 medical care providers and the 6,000,000 patients acknowledged by the FDA, accessing cannabis through a state-authorized medical cannabis recommendation, is a mountain of real-world experience. The FDA is making a conservative opinion based on evidence, but experience is what the FDA lacks; the DEA should be making their recommendation based on experience, law and evidence.

I ask the court to rule that the DEA reschedule cannabis to Schedule #5, reflecting its medicinal potential, the overwhelming evidence of its benefits as well as the experience of the millions of patients and their communities. This experience includes state panels dedicated to hearings on a myriad of cannabis subject matters. The conclusion of these many million human-hours in the many states have resulted in what we experience today, a consensus around handling cannabis as an over the counter medication. I have participated in some of these state processes and can attest to the professionalism of the membership and the seriousness under which they carried out their tasks. These are well thought through experience based recommendations that stand toe to toe with any evidence based evaluation of the FDA.

Background documents & Links:

'Cannabis' ontologies: Conceptual issues with Cannabis and cannabinoids terminology :

https://journals.sagepub.com/doi/10.1177/2050324520945797

Cannabis amnesia – Indian hemp parley at the Office International d'Hygiène Publique in 1935:

https://www.researchgate.net/publication/360540702_Cannabis_amnesia_-_Indian_hemp_parley_at_the_Office_International_d'Hygiene_Publique_in_1935

Veterans Action Council Green Paper:

https://www.veteransactioncouncil.com/the-green-paper-1

###

Perkins Coie

porterwright

September 26, 2024

VIA ELECTRONIC SUBMISSION – NPRM@DEA.GOV

Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Notice of Appearance (Docket No. DEA-1362)

Administrator Milgram:

Please take notice that MedPharm requests to appear in the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the "Proposed Rule"), if DEA grants MedPharm's request to participate in the hearing scheduled for December 2, 2024.

(A) MedPharm has standing to participate in a hearing. MedPharm is an "interested person" and falls within the CSA's zone of interests. Further, MedPharm will be directly and "adversely affected" or "aggrieved" by the Proposed Rule if finalized. MedPharm's status as an "interested person" is further detailed in the enclosed submission.

(B) MedPharm has unique expertise and would provide invaluable insights into: (i) whether the Proposed Rule sets forth substantial evidence that marijuana's potential for abuse is comparable to substances in schedule III; and (ii) whether DEA must or should adopt additional regulations to ensure compliance with the Single Convention on Narcotic Drugs of 1961. Further detail about the issues on which MedPharm desires to be heard is provided in the enclosed submission.

(C) MedPharm is uniquely situated to assist DEA's administrative decision making. DEA sought comments related to "additional controls" it is contemplating to ensure compliance with the Single Convention. Proposed Rule at 44,599. As a DEA-registered schedule I marijuana researcher, MedPharm has extensive knowledge and expertise regarding the impacts of existing and potential controls. Furthermore, MedPharm's own experience and research will assist DEA's assessment of marijuana's abuse potential. MedPharm's positions with regard to the particular objections or issues are further detailed in the enclosed submission.

All notices to be sent pursuant to this appearance should be addressed to the attorneys at the addresses provided below.

Respectfully yours,

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Enclosure

Perkins Coie

porterwright

September 26, 2024

VIA ELECTRONIC SUBMISSION – NPRM@DEA.GOV

Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Request to Participate in a Hearing & Notice of Appearance
(Docket No. DEA-1362)
Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Administrator Milgram:

Pursuant to 21 C.F.R. § 1308.44(c) and § 1316.48, MedPharm, a DEA-registered schedule I marijuana researcher focused on marijuana's potential medical utility, submits, as an "interested person," this Request to Participate in a Hearing and Notice of Appearance at the hearing scheduled for December 2, 2024. *See Notice of Hearing on Proposed Rulemaking*, 89 Fed. Reg. 70,148 (Aug. 29, 2024) ("Notice of Hearing"). Pursuant to any pre-hearing scheduling order, MedPharm will submit declarations supporting expert and fact witness testimony.

Introduction

On May 21, 2024, the United States Department of Justice ("DOJ") issued a Notice of Proposed Rulemaking proposing to transfer marijuana from schedule I of the Controlled Substances Act ("CSA") to schedule III. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44,597 ("Proposed Rule"). The Proposed Rule noted that DEA may hold a hearing to "receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III on the list of controlled substances." *Id*. at 44,599 (cleaned up).

The agency has since announced that it will hold such a hearing on December 2, 2024. *See* Notice of Hearing, 89 Fed. Reg. at 70,148. Concurrently, the agency is considering "marijuana-specific controls that would be necessary to comply with relevant treaty obligations in the event that, after the hearing, a final order reschedules marijuana." Proposed Rule at 44,599. DEA will presumably consider any such updated controls during this rulemaking. MedPharm is an interested person and, consistent with 21 C.F.R. §§ 1308.44(b) and 1316.48, is filing with the DEA Administrator this written notice of its intention to participate in the upcoming hearing.

MedPharm is a DEA-registered schedule I marijuana researcher focused on marijuana's potential medical utility for the treatment of neurodegenerative diseases such as Alzheimer's and Parkinson's. It also applied for DEA registration as a marijuana bulk grower in 2016. Its application remains unresolved and pending for decision before DEA. MedPharm values its DEA license and its collaborative relationship with DEA and believes a strong working relationship between MedPharm and DEA benefits both parties and the general public.

MedPharm has invested several years of time and significant monetary resources into establishing the first of its kind research and production facility. It has implemented Current Good Manufacturing Practices (cGMP), Good Agricultural and Collection Practices (GACP), and ISO17025. It is also Hazardous Materials and Handling audited and accredited. In addition, MedPharm has spent years collaborating with the University of Iowa's Department of Neurology, School of Public Health and the Institute for Clinical and Translational Science to organize and prepare to conduct a unique clinical trial with marijuana. Its research team has several sources of research funding, including, for example, grant funding from the Institute of Cannabis Research at Colorado State University-Pueblo, where it collaborates with research teams from CU-Anschutz and CU-Change at the University of Colorado-Boulder to investigate the quality of products within Colorado's adult-use marijuana marketplace.

Lastly, MedPharm has worked with Colorado State University on a recent National Institutes of Health application looking at intoxicated driving effects of co-administration of cannabis and alcohol in addition to work with Northwestern University examining the effects of cannabinoids on traumatic brain injuries.

While MedPharm supports transferring marijuana to schedule III, IV, or V—or even descheduling it entirely—under the Proposed Rule as written, MedPharm could face new, different, and potentially burdensome regulatory compliance obligations under additional marijuana-specific DEA regulations that the agency is apparently considering but has, as of yet, not described with any particularity.

These unnamed additional controls aside, MedPharm stands to benefit from the Proposed Rule's contemplated transfer of marijuana to schedule III. As DEA is aware, the controls applicable to schedule III substances are, in many important ways, less restrictive than those applicable to substances in schedules I and II. Accordingly, the Proposed Rule would also adversely affect and aggrieve MedPharm if it were to result in a final rule maintaining marijuana's schedule I placement or transferring it to schedule II.

MedPharm is prepared to offer testimony on a range of topics, including those

presented herein. For example, Dr. Duncan Mackie is a DEA-licensed researcher, earning his PhD from the University of Iowa School of Pharmacy in medicinal and natural products chemistry. He is currently the director of pharmacology and experimental therapeutics at MedPharm Holdings, where he is responsible for all research and development activities surrounding MedPharm's long-standing interest in phytocannabinoids, neuropharmacology, and neurodegenerative diseases. He is an expert in drug discovery, pharmacology, medicinal chemistry, cellular/molecular biology, and models of human diseases.

(A) Statement of Interest

The Proposed Rule is a "scheduling action" under 21 U.S.C. § 811(a). *See* Proposed Rule at 44,598; *id*. at 44,621. The Administrative Procedure Act ("APA"), the CSA, and DEA regulations set out the governing standards for this scheduling action and related rulemaking proceedings. *See id*. at 44,598–99.

Under the APA, 5 U.S.C. § 555(b), "an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding," "[s]o far as the orderly conduct of public business permits." DEA regulations accordingly provide that an "interested person" may file a request to participate in a hearing. 21 C.F.R. § 1308.44(c).

DEA regulations, in turn, define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. § 811]." 21 C.F.R. § 1300.01(b).[1] As the Proposed Rule was promulgated under 21 U.S.C. § 811(a), DEA's definition of "interested person" may apply here. *See* Proposed Rule at 44,598; *id*. at 44,621. DEA has not formally defined "adversely affected or aggrieved" for purposes of the definition of an "interested person." *See In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022) at 2 ("ALJ Order").[2] In recent scheduling actions, however, DEA has argued that a person qualifies as an "interested person" only if they can demonstrate the equivalent of Article III standing to pursue litigation in federal court. *See* ALJ Order at 4. ALJs have correctly rejected that argument, however, concluding instead that it is sufficient that a person falls within the CSA's "zone of interests." *See id*. at 5–6. As the discussion that follows demonstrates, under either standard, MedPharm qualifies as an interested person.

***First*, MedPharm falls within the CSA's "zone of interests."** In May 2022, a DEA ALJ concluded that the test for whether a particular entity is "adversely affected or

[1] Pursuant to 21 C.F.R. § 1300.01(b), "person" includes "any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity."
[2] The ALJ Order is attached here as Exhibit A.

aggrieved" by a proposed scheduling action (and thus qualifies as an "interested person" under DEA's definition of that term) was satisfied when the person "ha[s] an interest in the[] proceedings" that is "arguably within the zone of interests" of § 811(a) of the CSA. ALJ Order at 5 (quoting *PDK Lab'ys Inc. v. DEA*, 362 F.3d 786, 791 (D.C. Cir. 2004) (quoting *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970))). Given Congress' intent to "make agency action presumptively reviewable," the "zone of interests" test is "not meant to be especially demanding." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (citation omitted).

A party falls "within the zone of interests," the ALJ explained, "if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question." ALJ Order at 5 (quoting *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998)). With regard to the CSA, the Supreme Court has emphasized that the statute was enacted with "the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Oregon,* 546 U.S. 243, 250 (2005).

Under that standard, MedPharm falls within the CSA's zone of interests and therefore qualifies as an interested person. MedPharm is a DEA-registered marijuana researcher with ongoing marijuana research projects. It has invested significant time and money into developing the capabilities and relationships necessary to conduct cutting-edge marijuana research in full compliance with federal law.

Whether DEA ultimately adopts the Proposed Rule and transfers marijuana to schedule III or rejects it in favor of some other classification, the regulatory requirements applicable to marijuana in the wake of that decision will bear directly on the work MedPharm is currently doing under its DEA registration. It is, in short, the quintessential example of an entity that is a "target" of the regulations at issue here. *Compare, e.g.*, ALJ Order at 7–9 (recognizing the "interested person" status of multiple entities based on nearly identical considerations).

***Second*, in the event that the Article III standing requirements govern "interested person" status, MedPharm would still qualify**. Under that standard, MedPharm would need to demonstrate that it would be "adversely affected or aggrieved" by the Proposed Rule in a way that would support a claim to suffering an "injury in fact" for purposes of sustaining standing to sue in federal court. As explained in greater detail below, while MedPharm supports DOJ's proposal to transfer marijuana to schedule III and believes that outcome to be a momentous step in the right direction for federal marijuana policy, its own view is that marijuana does not belong on the CSA's schedules at all. As such, unless DEA ultimately deschedules marijuana, any action it takes on the Proposed Rule would adversely affect MedPharm.

As long as marijuana remains listed as a controlled substance at all—regardless of what CSA schedule it is on—MedPharm will remain subject to arduous regulatory requirements that will require it to maintain registration with DEA to continue its work. Maintaining DEA registration to research a controlled substance is costly, and complying with the regulatory requirements associated with registration is even more so. While transferring marijuana to schedule III would relax a few of those requirements incrementally, MedPharm would still face significant additional costs of doing business because of marijuana's status as a controlled substance. It would therefore have no choice but to pay the high price of compliance or else risk criminal penalties under the CSA.

MedPharm would be especially aggrieved if DEA were to reject the Proposed Rule in favor of either maintaining marijuana's schedule I classification or transferring it to schedule II. A number of regulatory requirements applicable to schedule I and II substances are significantly stricter than those applicable to substances in schedule III, including, for example:

- Research with schedule I substances requires an FDA-approved protocol—an arduous and costly requirement that does not apply to research with substances in any other schedule. *See* 21 C.F.R. § 1301.18.

- The inventory requirements for substances in schedules I and II are significantly stricter than those applicable to substances in schedule III. *See id.* § 1304.11(e)(6).

- The export requirements that would apply to marijuana were it transferred to schedule III are significantly less strict than those currently applicable under schedule I. *See id.* § 1312.21.

- The restrictions on orders for schedule I and II substances are significantly stricter than those applicable to substances in schedule III. *See, e.g.*, *id.* §§ 1305.04 and 1305.21.

- The storage requirements applicable to schedule I substances are significantly more burdensome than those that apply to substances in schedule III. *See id.* § 1301.71.

Each of these regulatory hurdles makes life harder for MedPharm as a researcher. Marijuana research is urgently needed, but conducting that research in compliance with federal law is extremely costly and time-consuming. Loosening these restrictions would therefore accelerate and enhance MedPharm's ability to complete its important work

and enable it to take on additional projects. Costly regulatory burdens like these are precisely the sort of "injury in fact" that Article III courts routinely hold are sufficient to demonstrate that a party is adversely affected or aggrieved for purposes of assessing standing to bring suit in federal court. *See, e.g.*, *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 457–58 (D.C. Cir. 2012) (party not directly regulated by agency rule had standing based on increased compliance costs resulting from regulation of a different party); *Metro. Wash. Chapter, Associated Builders & Contrs., Inc. v. District of Columbia*, 62 F.4th 567, 573 (D.C. Cir. 2023) ("Miller & Long can bring this action in its own right based on its allegations that it incurs increased administrative costs to comply with the statute's hiring and reporting requirements. . . .") (citing cases).

Moreover, transferring marijuana to schedule III would reduce the stigma associated with handling and researching a schedule I substance while simultaneously eliminating the tax penalty associated with "trafficking" in marijuana under 26 U.S.C. § 280E. These shifts in public perception and tax penalties would free up significant capital for regulated marijuana companies and those interested in the safety and quality of products available in the state-regulated markets to invest in the sort of gold-standard, federally legal marijuana research that MedPharm has worked so hard to position itself to conduct. A DEA decision to keep marijuana in schedule I or transfer it to schedule II would therefore directly undercut MedPharm's economic interests as well—another injury in fact sufficient to support interested person status even under the strictest Article III standard.

Finally, the "additional controls" DEA is contemplating to ensure compliance with the Single Convention also adversely affect and aggrieve MedPharm. Concurrent with the administrative process to reconsider marijuana's schedule I status under the CSA, DEA has announced that it is also considering marijuana-specific controls associated with international treaty obligations. Proposed Rule at 44,599. The Office of Legal Counsel ("OLC") concluded that "additional controls pursuant to the CSA's regulatory authorities" may be necessary. OLC, *Questions Related to the Potential Rescheduling of Marijuana,* at 4 (Apr. 11, 2024).[3]

While MedPharm does not know any details regarding what "additional controls" DEA has in mind, any additional requirements beyond those applicable to schedule III substances generally would impose burdensome and costly regulatory barriers to the urgently-needed research MedPharm seeks to complete. Such additional costs would, among other things, adversely impact MedPharm's current research projects, the day-to-day operation of the company's research arm, and the company's ability to undertake additional and equally urgent research projects going forward. These barriers to MedPharm's research endeavors will ultimately undermine public health and safety

[3] This OLC opinion is attached as Exhibit B.

generally by delaying the development and FDA-approval of potentially life-saving marijuana-related treatments and impeding MedPharm's ongoing efforts to provide important public health and safety data on the marijuana products consumers are actually using under Colorado law. These injuries undermine MedPharm's business goals and its core mission more generally and thus provide an independent basis for MedPharm's interested person status even if Article III standards control.

(B) Objections/Issues

1. Whether the Proposed Rule sets forth substantial evidence that marijuana's potential for abuse is comparable to substances in schedule III.

2. Whether DEA must or should adopt additional regulations to ensure compliance with the Single Convention on Narcotic Drugs of 1961.

(C) Statement of Positions on Objections/Issues

1. The Proposed Rule does not set forth substantial evidence that marijuana has abuse potential higher than substances in schedules IV or V.

Neither the Proposed Rule nor the supporting materials presents *substantial* evidence that marijuana's abuse potential is higher than that of substances in schedules IV or V. A drug in schedule V has a low potential for abuse and limited physical dependence or psychological dependence relative to the drugs in schedule IV. Compared to benzodiazapenes in schedule IV, marijuana has a low potential for abuse and lower psychological dependence. Marijuana use may produce some level of dependence, and cessation of use may produce withdrawal symptoms.[4] But dependence associated with marijuana use and marijuana withdrawal is far less significant than benzodiazepine dependence and benzodiazepine withdrawal.[5]

MedPharm's own experience and research, along with other emerging research that has come to light since the comment period on the Proposed Rule closed, confirms and strengthens this conclusion. Experts from MedPharm are prepared to present evidence and expert testimony on the issue of abuse potential and medical use in treatment in the United States, including Dr. Duncan Mackie, a DEA licensed researcher who earned his

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[4] *See, e.g.* Jason P. Connor, et al., *Cannabis use and cannabis use disorder*, 7 NATURE REVIEWS DISEASE PRIMERS 16 (Feb. 25, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8655458/.
[5] *Compare* Connor, *supra* note 4, *with* Lone Baandrup, et al., *Pharmacological interventions for benzodiazepine discontinuation in chronic benzodiazepine users*, 3 COCHRANE DATABASE OF SYSTEMATIC REVIEWS 3 (Mar. 15, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6513394/.

Ph.D. from the University of Iowa School of Pharmacy in Medicinal and Natural Products Chemistry. He is currently the Director of Pharmacology and Experimental Therapeutics at MedPharm Holdings, where he is responsible for all research and development activities surrounding MedPharm's long standing interest in phytocannabinoids, neuropharmacology, and neurodegenerative diseases. Dr. Mackie is an expert in drug discovery, pharmacology, medicinal chemistry, cellular/molecular biology, and models of human diseases.

Equally important, marijuana is treated differently from drugs of abuse listed in schedules I–V. Every year Congress prohibits DOJ from spending funds to interfere with state medical marijuana programs. The Attorney General recently confirmed that marijuana enforcement continues to be a low priority for DOJ. Indeed, it is difficult to fathom how DEA could summon the resources necessary to faithfully enforce the CSA as long as marijuana remains a controlled substance, even if Congress were to permit it to do so.

Taken together, the longstanding non-enforcement position of Congress and the Executive Branch with respect to marijuana powerfully supports the conclusion that marijuana's abuse potential is—compared to other controlled substances listed on the CSA's schedules at least—relatively low. Put simply, whatever Congress meant by "high potential for abuse," these considerations provide powerful support for the conclusion that it did not mean for the term to apply to marijuana.

2. DEA should not impose additional regulations on marijuana to ensure compliance with the Single Convention on Narcotic Drugs of 1961.

Because the statutory basis for considering treaty compliance in the scheduling process is itself unconstitutional, DEA lacks authority to impose additional controls to ensure treaty compliance. 21 U.S.C. § 811(d)(1) is unconstitutional because it violates the private non-delegation doctrine.[6]

Even if § 811(d)(1) were constitutional, however, DEA still should not impose additional regulatory requirements on marijuana in the name of treaty compliance because no matter what requirements it imposes, the U.S. will remain out of compliance with the Single Convention due to the existence of several state-regulated adult-use marijuana markets across the country. Additionally, while any additional requirements would do

[6] *See* Shane Pennington and Matthew C. Zorn, *The Controlled Substances Act: An International Private Delegation That Goes Too Far*, 100 Wash. U. L. Rev. 29 (2023), https://wustllawreview.org/2023/05/19/the-controlled-substances-act-an-international-private-delegation-that-goes-too-far/.

nothing to prevent that ongoing non-compliance, they *would*—for reasons described in detail above—impede marijuana research and the advancement of the now-recognized medical use of marijuana through FDA research and development efforts like those MedPharm has pursued and remains committed to. Given the priority the Single Convention places on the advancement of science and medical use of substances, such an outcome would be perverse.

For all the forgoing reasons, MedPharm is an interested person and requests to participate in DEA's administrative law judge hearing scheduled for December 2, 2024. All notices and correspondence to be sent pursuant to this appearance should be addressed to me at the address provided below.

Respectfully yours,

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Enclosures

- Exhibit A: *In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022)
- Exhibit B: OLC, *Questions Related to the Potential Rescheduling of Marijuana* (Apr. 11, 2024)

Exhibit A

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT**	**Docket No. 22-15**

ORDER GRANTING IN PART GOVERNMENT'S MOTION TO DISMISS IN PART

On January 14, 2022, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM), with the docket number DEA-623, titled "Schedules of Controlled Substances: Placement of 4-hydroxy-*N,N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-*alpha*-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N,N*-diethyltryptamine (5-MeO-DET), and *N,N*-diisopropyltryptamine (DiPT) in Schedule I." 87 Fed. Reg. 2376 (2022). The NPRM proposes to place the five tryptamine hallucinogens (4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT) in schedule I of the Controlled Substances Act (CSA). *Id.* On January 31, 2022, Panacea Plant Sciences (Panacea) filed a Request for Hearing (RFH). On February 14, 2022, Jason Wallach and Hamilton Morris, Kykeon Biotechnologies Inc. (Mindstate) and Tactogen Inc. (Tactogen), and Amy Rising filed RFHs.

On April 18, 2022, the Government filed its Motion to Dismiss in Part (Government's Motion) alleging that not all parties requesting a hearing have standing and asking this tribunal to dismiss "any party that cannot establish interested person status for at least one of the substances[.]"[1] Gov't Mot. at 1. Additionally, the Government requests that this tribunal "limit

[1] The Government concedes that Jason Wallach and Hamilton Morris, who are proceeding jointly, established standing in their RFH with respect to DiPT. Gov't Mot. at 9. In the April 26, 2022 status conference, counsel for Dr. Wallach and Mr. Morris indicated that they only intended to request a hearing with respect to the proposed scheduling of DiPT and do not wish to challenge the proposed scheduling of the other four tryptamines. Accordingly, Dr. Wallach and Mr. Morris' standing to challenge the proposed scheduling of DiPT is not challenged herein.

the hearing on this proposed rulemaking to those substances for which an interested person has requested a hearing." *Id.* at 1-2.

ADMINISTRATIVE STANDING

"The starting point in determining administrative standing should be the language of the statutes and regulations that provide for an administrative hearing, appeal or intervention." *Koniag, Inc., Uyak v. Andrus*, 580 F.2d 601, 614 (D.C. Cir. 1978) (Bazelon, J., concurring); *see Koniag*, 580 F.2d at 606. The standing analysis is thus an individualized one, within the context of the regulations and the statutory scheme as a whole. *Nichols v. Bd. of Trs.*, 835 F.2d 881, 896 n.108 (D.C. Cir. 1987).

This is a scheduling proceeding under § 811 of the CSA. The regulations governing scheduling proceedings provide that an "interested person" may request a hearing on the proposed scheduling of a substance. *See* 21 C.F.R. § 1308.44. The regulations define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant" to 21 U.S.C. § 811. *Id.* § 1300.01. A person requesting a hearing must state "with particularity" his interest in the proceeding. *Id.* § 1316.47(a).

The Agency has not interpreted either "interested person" or "any person adversely affected or aggrieved," although there are two Agency rulemaking proceedings in which the Agency found a party requesting a hearing did not meet the definition of "interested person." *See Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. 26701, 26703 (2013) (denying a request for hearing because a concern that the substance had a large potential for abuse was insufficient to show that the party requesting a hearing was an "interested person"); *Schedules of Controlled Substances: Placement of Lacosamide into Schedule V*, 74 Fed. Reg. 23789, 23789 (2009) (denying a request for hearing because the party's statement that "lack of information and inappropriate comparisons to other drugs precluded the scheduling" did not sufficiently establish standing as an "interested person").

In the absence of an official Agency interpretation, this tribunal looks to general principles on standing. Standing to sue in federal court stems from the Article III case or controversy requirement and thus requires injury-in-fact. *See, e.g.*, *Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338-39 (2016). Moreover, federal courts have put on a "judicial gloss" of prudential standing called the "zone of interests" test limiting who may challenge an agency action. *See Animal Legal Def. Fund v. Espy*, 23 F.3d 496, 502 (D.C. Cir. 1994). But standing before an administrative agency is

more permissive than before an Article III court. *See Gettman v. DEA*, 290 F.3d 430, 434 (D.C. Cir. 2002) ("Because agencies are not constrained by Article III, they may permit persons to intervene in the agency proceedings who would not have standing to seek judicial review of the agency action."); *Envirocare, Inc. v. NRC*, 194 F.3d 72, 74 (D.C. Cir. 1999) ("Agencies, of course, are not constrained by Article III of the Constitution; nor are they governed by judicially-created standing doctrines restricting access to the federal courts. The criteria for establishing 'administrative standing' therefore may permissibly be less demanding than the criteria for 'judicial standing.'"); *Nichols*, 835 F.2d at 896 n.108 ("We emphasize that parties may validly participate in agency proceedings even absent standing to obtain judicial review."); *Koniag*, 580 F.2d at 606 (a party need not be "excluded from participation before the agency if it does not have a sufficient interest to meet Article III requirements for judicial review.").

Applying the "'interested person' concept to parties not entitled to judicial review resists precise legislative or judicial delineation, and requires close scrutiny, in the context of the statutory and regulatory schemes governing the proceedings in which intervention is sought, of the private interest asserted." *Nichols*, 835 F.2d at 896 n.108 (internal citations omitted). Thus, standing before an agency is not synonymous with standing before a federal court and requires a close examination of the applicable regulations. *Id.*; *see also Koniag,* 580 F.2d at 614. More precisely, the question here is what "adversely affected or aggrieved" requires within the context of the CSA and the limited Agency caselaw for standing in these proceedings.

The Agency has taken the position, in the context of mootness, that it is not bound by Article III. *See, e.g.*, *The Pharmacy Place*, 86 Fed. Reg. 21008, 21008 (2021); *Jeffrey D. Olsen, M.D.*, 84 Fed. Reg. 68474, 68476 (2019).

> The subject matter of agencies' jurisdiction naturally is not confined to cases or controversies inasmuch as agencies are creatures of [A]rticle I. Though agencies must act without arbitrariness, . . . still agencies are generally free to act in advisory or legislative capacities…[which] is obvious in the case of rulemaking[.]

Olsen, 84 Fed. Reg. at 68478 (quoting *Tennessee Gas Pipeline v. Fed. Power Comm'n*, 606 F.2d 1373, 1379 (D.C. Cir. 1979)). While not directly on point, the Agency's position is instructive given that courts have routinely stated that (with some caveats): "the doctrine of mootness can be described as the doctrine of standing set in a time frame: The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness)." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 189-90 (2000)

(internal quotations omitted) (noting exceptions to this rule). Given that the Administrator has rejected the application of Article III in the context of mootness in Agency proceedings, the logical extrapolation of those decisions is that § 1300.01 does not incorporate the requirements of Article III standing.

The Government, however, argues that "adversely affected or aggrieved" applies no differently here than how it has historically been interpreted in federal courts. Gov't Mot. at 4-5. "The phrase 'person adversely affected or aggrieved' is a term of art used in many statutes to designate those who have ***standing to challenge*** or appeal an agency decision, ***within the agency*** or before the courts." *Id*. at 4 n.1 (emphasis in original) (quoting *Dir., Off. of Workers' Comp. Programs, Dept. of Lab. v. Newport News Shipbuilding and Dry Dock Co. (Newport News)*, 514 U.S. 122, 126 (1995)). The phrase appears in the judicial review provision of the Administrative Procedure Act (APA) and similarly appears in the CSA's judicial review provision. *See* 5 U.S.C. § 702 ("A person…adversely affected or aggrieved by agency action within the meaning of the relevant statute[] is entitled to judicial review thereof."); 21 U.S.C. § 877 ("any person aggrieved by a final decision of the Attorney General may obtain review of the decision"). Courts have interpreted the APA's judicial review provision as requiring a party to show that he is both "injured in fact by agency action and that the interest he seeks to vindicate is arguably within the 'zone of interests to be protected or regulated by the statute' in question." *Newport News*, 514 U.S. at 127 (quoting *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). Additionally, courts interpreting the CSA's judicial review provision have similarly found that it "merely requires that the litigant have Article III standing and prudential standing—i.e., arguably be within the 'zone of interests.'" *Bonds v. Tandy*, 457 F.3d 409, 413 (D.C. Cir. 2006); *see PDK Lab'ys Inc. v. DEA*, 362 F.3d 786, 793 (D.C. Cir. 2004).

The Government's interpretation of *Newport News*, however, is too broad. That decision—which involved federal judicial review—stands merely for the proposition that a party challenging an agency decision *in federal court* lacks standing unless the party can establish it had injury-in-fact and fell within the statute's zone of interests from the very beginning of the case, including before the Agency. *Newport News*, 514 U.S. at 126. But it does not support the proposition that a party must be excluded from *an agency proceeding* if it fails to make that showing. *See Gettman*, 290 F.3d at 434; *Koniag*, 580 F.2d at 606. Similarly unpersuasive are the other cases cited by the Government. While courts have interpreted "adversely affected or aggrieved" as requiring Article

III and prudential standing, those courts were examining statutory provisions establishing standing to seek judicial review before a federal court, not standing before an agency. *See Newport News*, 514 U.S. at 127; *Bonds*, 457 F.3d at 413; *PDK Lab'ys*, 362 F.3d at 793. As discussed above, courts have repeatedly rejected the presumption that Article III applies to agency proceedings, as has this Agency, in the context of mootness. Moreover, the Government's argument runs counter to the established principle that administrative standing is more permissive than Article III standing. *See Gettman*, 290 F.3d at 434. Accordingly, the Government's argument is unpersuasive.[2]

The parties find common ground on applying the zone of interests test, which provides that a party requesting a hearing must have an interest in these proceedings and that interest must be "arguably within the zone of interests…" *PDK Lab'ys*, 362 F.3d at 791 (quoting *Ass'n of Data Processing*, 397 U.S. at 153). The parties requesting a hearing have the burden of proving that they have standing to participate in these proceedings.[3] The test is "not meant to be especially demanding[;]" however, where the party is not the subject of the agency action, the party's interests must not be "so marginally related to or inconsistent with the purposes implicit in the statute." *Clarke v. Secs. Indus. Ass'n*., 479 U.S. 388, 399 (1987). A party falls "within the zone of interests if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question." *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998) (citing *First Nat'l Bank & Tr. Co. v. Nat'l Credit Union Admin*., 988 F.2d 1272, 1275 (D.C. Cir. 1993)). To be clear, "[j]udicially-devised prudential standing requirements, of which the 'zone of interests' test is one, are also inapplicable to an administrative agency…The doctrine of prudential standing, like that derived from the Constitution, rests on considerations 'about the proper—and properly limited—role of the courts in a democratic society.'" *Envirocare*, 194 F.3d at 75 (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). But, while prudential standing is not necessarily required for administrative standing, absent additional guidance from the Agency, the zone of interests standard provides an instructive framework to interpret the meaning of "adversely affected or aggrieved."

[2] Even if the regulations require injury-in-fact, that would not change the outcome of this case. *See infra* note 4.

[3] While 21 C.F.R. § 1316.56 provides that the moving party has the burden of proof, the regulations require that the party requesting a hearing demonstrate their interest in these proceedings at the outset. *See* 21 C.F.R. § 1316.47(a).

For these proceedings, the CSA and, specifically, § 811 establish the zone of interests. The overall purpose of the CSA is "to protect the public from the deleterious effects of the illegitimate use and distribution of controlled substances." *Bonds*, 457 F.3d at 415; *see Gonzales v. Oregon*, 546 U.S. 243, 250 (2005) (the CSA was enacted with "the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances"). To accomplish its purpose, "the CSA creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the [CSA's] five schedules." *Gonzales*, 546 U.S. at 250. Section 811 regulates how substances may be added, removed, or transferred between the five schedules. 21 U.S.C. § 811. The consequence of such action is that a party may be required to obtain a registration to handle a scheduled substance. 21 U.S.C. § 823; *see MD Pharm.*, 133 F.3d at 13 (the CSA "is a quintessential entry-restricting statute."). As the Government notes, "[r]esearch of controlled substances is within the class of activity regulated by the CSA." Gov't Mot. at 8. Therefore, the zone of interests encompassed by § 811 and the CSA as whole includes researchers who would be regulated by the scheduling of a particular substance.

ANALYSIS

For the following reasons, I find that Panacea, Mindstate, and Tactogen have met the regulatory definition of "interested person" and, thus, have standing to participate in these proceedings.[4] Ms. Rising, however, does not have standing as an "interested person." I also reject the Government's general proposition that an "interested person" may only address a tryptamine if it has established standing for that specific tryptamine.

[4] While not required, the parties requesting a hearing at issue, with the exception of Ms. Rising, can also show injury-in-fact. In its Partial Withdrawal of its Motion to Dismiss in Part (Government's Partial Withdrawal), the Government concedes that Tactogen can show injury-in-fact. Gov't Partial Withdrawal at 1-2. Further, as researchers, Panacea, Mindstate, and Tactogen would suffer economic harm if the tryptamines are scheduled because they would have to obtain a registration to continue their respective projects. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

1. Panacea Plant Sciences

In its RFH and Opposition to the Government's Motion, Panacea, as required by 21 C.F.R. § 1316.47(a), stated "with particularity" its interests in these proceedings.[5] *See* Panacea RFH at 3; Panacea Opp'n to Gov't Mot. at 2-3. Specifically, Panacea is a biotech company and has been studying, in collaboration with a Canadian company, the five tryptamines and "other similar compounds in order to treat conditions like depression, anxiety, post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI)." Panacea RFH at 1, 3. Panacea started a project with a doctor at the University of Massachusetts to develop medical therapies utilizing the five tryptamines and other compounds, but Panacea discontinued the project due to the "the potential of conflict and future scheduling." Panacea Opp'n to Gov't Mot. at 2. Additionally, Panacea has patent filings that cover the five tryptamines. *Id.* at 3. Panacea is also collaborating and contracting with other companies and universities to study the five tryptamines and develop therapies, so scheduling the tryptamines will require Panacea to apply for both a manufacturing and research DEA registration. *Id.* at 2-3. Obtaining a registration will be costly for Panacea and cause delays in its research and projects. *Id.*

Panacea meets the regulatory definition of "interested person" under the CSA, as scheduling any or all of the five tryptamines will adversely affect its interests and Panacea's interests fall within the CSA's zone of interests. Panacea falls within the zone of interests because it would be regulated by the scheduling of the five tryptamines; Panacea has ongoing research and projects involving the five tryptamines, and Panacea will be required to obtain a registration to continue its work if the tryptamines are scheduled. *See MD Pharm.*, 133 F.3d at 12-13; *First Nat'l Bank & Tr. Co.*, 988 F.2d at 1275. The potential added cost of obtaining a registration has already forced Panacea to discontinue one project and may require Panacea to discontinue other projects

[5] The Government argues that Panacea failed to state its interests in its RFH "with particularity," so, if this tribunal does not dismiss Panacea from these proceedings, the tribunal should require Panacea to provide a more detailed statement of its interests. Gov't Mot. at 11. Panacea's RFH provided substantially more detailed information regarding its interests than the two scheduling cases relied on by the Government where the Administrator found that the statements of interest lacked particularity. *Id.* (citing *Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703; *Placement of Lacosamide into Schedule V*, 74 Fed. Reg. at 23789). Panacea's Opposition to the Government's Motion further supplemented its statement of interests and provided this tribunal with sufficient information to determine whether Panacea is an "interested person." *See* Panacea Opp'n to Gov't Mot. at 2-3.

or increase the costs of those projects. Since the purpose of § 811 is to determine whether a substance should be scheduled, thereby bringing the substance under the purview of the CSA and restricting access to it, Panacea's interest in continuing to use the five tryptamines directly relates to the purpose of § 811. Therefore, Panacea has standing in these proceedings.

2. Mindstate and Tactogen

In their joint RFH and Opposition to the Government's Motion, Mindstate and Tactogen, as required by 21 C.F.R. § 1316.47(a), stated "with particularity" their interests in these proceedings.[6] *See* Mindstate & Tactogen RFH at 2; Mindstate & Tactogen Opp'n to Gov't Mot. at 3-4, Ex. A. Specifically, Mindstate is a research company that "develops psychedelic drug therapies for intractable mental health conditions" and is "currently investigating one or more of the Five Tryptamines in preclinical research." Mindstate & Tactogen RFH at 2. Mindstate is building a database of phenomenological and biochemical data on psychedelic compounds. Mindstate & Tactogen Opp'n to Gov't Mot. at 3. Mindstate must work with tryptamines to complete this project and other projects to develop and bring compounds to market. *Id.* at 4. Tactogen is a public benefit corporation "developing safer, more effective prescription medicines for mental wellness" and is "currently investigating one or more of the Five Tryptamines as part of a program to develop new medicines." Mindstate & Tactogen RFH at 2. Tactogen has had one published patent application under the Patent Cooperation Treaty on the use of tryptamines for mental disorders. Mindstate & Tactogen Opp'n to Gov't Mot. at 4.

Mindstate and Tactogen each qualify as an "interested person" under the CSA because scheduling any or all of the five tryptamines will adversely affect each of their interests and such interests fall within the zone of interests.[7] Mindstate and Tactogen fall within the CSA's zone of interests because they would be regulated by the scheduling of the five tryptamines. *See MD Pharm.*, 133 F.3d at 12-13; *First Nat'l Bank & Tr. Co.*, 988 F.2d at 1275. Both companies would

[6] The Government makes the same argument, as it did with respect to Panacea's RFH, that Mindstate and Tactogen's RFH lacked particularity. *See supra* note 5; Gov't Mot. at 12-13. Mindstate and Tactogen's RFH provided enough detail, and their Opposition to the Government's Motion further supplemented their statement of interests to determine if they are an "interested person." *See* Mindstate & Tactogen RFH at 2; Mindstate & Tactogen Opp'n to Gov't Mot. at 3-4, Ex. A.

[7] The Government concedes that Tactogen has established standing with respect to 5-MeO-MiPT. Gov't Partial Withdrawal at 1-2. The Government maintains that Tactogen has still not established standing with respect to the other four tryptamines. *Id.*

be required to obtain registrations to continue their respective projects; Mindstate's development of compounds for mental health conditions and Tactogen's development of therapies for mental wellness would be regulated by the CSA if the five tryptamines are scheduled. Like Panacea, Mindstate and Tactogen's interests in using the tryptamines directly relate to the purpose of § 811. Therefore, Mindstate and Tactogen have standing in these proceedings.

3. Amy Rising

In her RFH, Ms. Rising stated that the proposed scheduling of the five tryptamines "would result in barriers to research and the denial [of] life-saving healthcare to US patients" and that they should be placed in schedule V, not schedule I. Rising RFH at 1-2. In her Opposition to the Government's Motion, Ms. Rising stated that she met with the "senate DEA liaison and senate judiciary counsel at their request to discuss the upcoming renewal of the Fentanyl Analogues" several times between August and December 2019. Rising Opp'n to Gov't Mot. at 1-2. Additionally, the Food and Drug Administration "declared psilocybin a 'breakthrough therapy' for treatment-resistant depression." *Id.* at 1. Ms. Rising further indicated that the "National Institute on Drug Abuse Director" stated that obtaining a schedule I DEA registration is administratively challenging and time consuming, so scientists may be deterred from researching schedule I substances. *Id.* at 2. Ms. Rising concluded that she has interests in the scheduling status of the five tryptamines and placing them in schedule I will "impose greater burdens on research, create barriers to access and impose undue difficulty on policy makers…" *Id.*

Ms. Rising has failed to establish her interest in these proceedings. She has provided no information as to what her specific interest is, such as her career or credentials; rather, she simply asserts that she is interested. *See id.* at 2 ("Amy Rising has provided the example of her work and interests in the scheduling status of" the five tryptamines). The only example she has provided of her work is meetings with government officials regarding psilocybin and the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 S. 3201, 116th Cong. (2020), but she does not explain how the meetings related to the five tryptamines, let alone her role and purpose in those meetings. *See id.* She argues that scheduling the five tryptamines in schedule I will create barriers to research but offers no information as to how or why she is affected by potential barriers for research. *See id.* 2-3.

Ms. Rising's general assertion of interest does not meet the regulatory requirements that she both have an interest in these proceedings and that she state that interest "with particularity."

21 C.F.R §§ 1300.01(b), 1316.47(a); *see Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703 (denying a request for hearing because a person's generalized concern was insufficient to demonstrate an interest in the proceeding); *Placement of Lacosamide into Schedule V*, 74 Fed. Reg. at 23789 (same). Therefore, given Ms. Rising's failure to show her interest in these proceedings, she does not have standing to appear in these proceedings.

4. Standing as to Individual Tryptamines

The Government argues that this tribunal should further limit standing in two respects: (1) it should only allow a hearing on those tryptamines for which parties have standing; and (2) an "interested person" should only be allowed to contest a tryptamine for which it has established standing. Gov't Mot. at 6-7. The Government argues that, while the tryptamines are similar and consolidated into one NPRM, there will be five distinct rules. *Id.* The Government cites no support for the proposition that one NPRM and one rulemaking process results in distinct rules.[8] Additionally, 21 C.F.R. § 1300.01 defines "interested person" as "any person adversely affected or aggrieved *by any rule or proposed rule*…" (emphasis added). There is one proposed rule,[9] not five, so any person adversely affected or aggrieved by the scheduling of one of the tryptamines has standing to challenge the proposed rule in its entirety.

Moreover, the Administrator opted to combine the five tryptamines into one rulemaking process and did so, in part, because of the similarity of those substances to each other and to already-controlled substances. NPRM, 87 Fed. Reg. at 2378. Additionally, the NPRM (as well as the Department of Health and Human Services evaluations and recommendations) includes scientific references that deal generally with tryptamines and compare the substances to each other and already-controlled substances. *Id*. at 2378-81. On this basis, a wholesale limitation of the parties is unjustified and would prove impractical at the merits hearing; it would be incongruous to parse the rulemaking process when the Agency has chosen to proceed under one proposed rule.

[8] The Government does cite 21 U.S.C. § 811(a)(1); however, § 811(a)(1) provides only that the Attorney General may schedule a substance if he makes findings as to such substance. *See* Gov't Mot. at 6. Section 811(a)(1) is silent as to standing for an "interested person" to challenge those findings and whether one rulemaking process for multiple substances results in distinct rules or one rule encompassing multiple substances.

[9] The NPRM also repeatedly states that it is one "proposed action," not five. *See* NPRM, 76 Fed. Reg. at 2376-78, 2381-82.

Further, even if I were to accept the Government's proposition that each "interested person" must have standing with respect to each tryptamine to fully participate in these proceedings, Panacea, Mindstate, and Tactogen have established standing for all five of the tryptamines. Panacea expressly stated that it is researching the five tryptamines, so scheduling any or all of the tryptamines will adversely affect Panacea. Panacea Opp'n to Gov't Mot. at 2-3. The Government concedes that Tactogen is an "interested person" with respect to 5-MeO-MiPT (Gov't Partial Withdrawal at 1-2), and Mindstate is currently utilizing 5-MeO-MiPT and 4-OH-DiPT (Mindstate & Tactogen Opp'n to Gov't Mot., Ex. A at 2). Both companies are arguably within the zone of interests for the other tryptamines because their research and projects will be limited, as the other tryptamines are analogues or related to hallucinogenic substances that the companies are currently studying. Mindstate & Tactogen Opp'n to Gov't Mot. at 14. In sum, the zone of interests test is not meant to be demanding nor are Mindstate and Tactogen's interests inconsistent with the purpose of § 811. *See Clarke*, 479 U.S. at 399; *MD Pharm.*, 133 F.3d at 12-13. Therefore, I reject the Government's argument to partition the hearing by tryptamine and "interested person."

CONCLUSION

Accordingly, the Government's Motion is **GRANTED IN PART** and **DENIED IN PART**. The Government's Motion is **GRANTED** with respect to Amy Rising and **DENIED** with respect to Panacea, Mindstate, and Tactogen.

Dated: May 6, 2022

TERESA A. WALLBAUM
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on May 6, 2022, caused a copy of the foregoing to be delivered to the following recipients:

(1) John E. Beerbower, Esq., Counsel for the Government, via email at John.E.Beerbower@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov;
(2) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;
(3) John T. Hunter, Esq., Counsel for Jason Wallach and Hamilton Morris, via email at john@hljdefense.com;
(4) Matt Baggott, Tactogen Inc., via email at matt@tactogen.com;
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(8) Amy Rising, via email at amynicholerising@gmail.com.

Aniayah S. Beckford
Staff Assistant to Judge Wallbaum

Exhibit B

Questions Related to the Potential Rescheduling of Marijuana

The approach that the Drug Enforcement Administration currently uses to determine whether a drug has a "currently accepted medical use in treatment in the United States" under the Controlled Substances Act is impermissibly narrow. An alternative, two-part inquiry proposed by the Department of Health and Human Services is sufficient to establish that a drug has a "currently accepted medical use" even if the drug would not satisfy DEA's current approach.

Under 21 U.S.C. § 811(b), a recommendation by HHS that a drug has or lacks a "currently acceptable medical use" does not bind DEA. In contrast, the scientific and medical determinations that underlie HHS's "currently acceptable medical use" recommendation are binding on DEA, but only until the initiation of formal rulemaking proceedings to schedule a drug. Once DEA initiates a formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.

Neither the Single Convention on Narcotic Drugs nor the CSA requires marijuana to be placed into Schedule I or II of the CSA. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific restrictions that follow from a drug's placement on a particular schedule. As a result, DEA may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the CSA's regulatory authorities.

April 11, 2024

MEMORANDUM OPINION FOR THE ATTORNEY GENERAL

The Controlled Substances Act ("CSA")[1] imposes a unified framework for controlling drugs and other substances that are found to pose a risk of abuse.[2] In doing so, it seeks to balance several, often competing, interests. These interests include ensuring the availability of drugs that "have a

[1] In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, the provisions of which are codified at Chapter 13 of Title 21 of the U.S. Code. The Act comprised several titles, including Title II, which it called the Controlled Substances Act, and Title III, which it called the Controlled Substances Import and Export Act. For ease of reference, we refer to the entire 1970 law as the CSA.

[2] The CSA applies to both drugs and "other substance[s]" that have been controlled. *See* 21 U.S.C. § 802(6). For ease of reference, we use the term "drug" to refer to both.

useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people"; preventing the "illegal importation, manufacture, distribution, and possession and improper use of controlled substances [that] have a substantial and detrimental effect on the health and general welfare of the American people"; and ensuring that the United States complies with "international conventions designed to establish effective control over international and domestic traffic in controlled substances." 21 U.S.C. § 801(1), (2), (7).

The CSA balances these purposes by placing each drug warranting control into one of five "schedules," with drugs in Schedule I subject to the strictest regulatory and criminal provisions, and drugs in Schedule V subject to the least strict. *See generally* 21 U.S.C. §§ 821–832, 841–865, 951–971. The CSA further authorizes the Attorney General to add, transfer, and remove drugs from the schedules using formal rulemaking procedures, *see id.* §§ 811, 812, and otherwise grants the Attorney General broad authority to take regulatory action consistent with the Act, *see, e.g.*, *id.* §§ 821, 871(b). The Attorney General has in turn generally delegated these functions to the Administrator of the Drug Enforcement Administration ("DEA"). 28 C.F.R. § 0.100(b).

Marijuana has been a Schedule I drug since Congress enacted the CSA. *See* 21 U.S.C. § 812(c). To reschedule marijuana from Schedule I, DEA would need to determine, among other things, that the drug has a "currently accepted medical use in treatment in the United States" ("CAMU"). *Id.* § 812(b). Since 1992, however, DEA has determined that a drug has a CAMU only if either the Food and Drug Administration ("FDA") has approved the drug for marketing in interstate commerce under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, or the drug meets a five-part test that tracks the "core standards developed under the FDCA." 57 Fed. Reg. 10,499, 10,503–04, 10,506 (Mar. 26, 1992). And because FDA has not approved marijuana and DEA has determined that marijuana does not meet its five-part test, DEA has repeatedly rejected petitions to move marijuana to a less restrictive schedule.

On October 6, 2022, President Biden asked the Secretary of Health and Human Services ("Secretary") and the Attorney General to initiate an "administrative process to review expeditiously how marijuana is scheduled under federal law." *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), https://www.whitehouse.gov/briefing-room/

statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform. The CSA requires the Secretary to provide certain recommendations before the initiation of proceedings to schedule or reschedule a drug, and the statute provides that the Secretary's recommendations "shall be binding" as to certain "scientific and medical matters." 21 U.S.C. § 811(b).

Consistent with this requirement, in 2023, the Department of Health and Human Services ("HHS") recommended that DEA reschedule marijuana to Schedule III. *See* Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (Aug. 29, 2023). HHS concluded that, regardless of whether a drug was approved by FDA or satisfied DEA's five-part test, the drug could have a CAMU if it satisfied a new, two-part inquiry. Part 1 of that inquiry asks whether licensed health care providers have "widespread current experience with medical use" of the drug "in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine." Memorandum for the Commissioner, FDA, from the Assistant Secretary for Health, HHS, *Re: Part 1 Analysis* at 1 (July 17, 2023) ("HHS Part 1 Analysis Memo"). If so, Part 2 of the inquiry asks whether there is "some credible scientific support for at least one of the medical uses." *Id.* at 2.

Against this backdrop, you have asked us three questions:[3]

> (1) If a drug satisfies the two-part inquiry employed by HHS, does that establish a currently accepted medical use under the statute even if the drug has not been approved by FDA and even if the drug does not satisfy DEA's five-part test?
>
> (2) To what extent do the "scientific and medical matters" referenced in 21 U.S.C. § 811(b), which are binding upon the Attorney General,

[3] This opinion memorializes advice we provided you on February 16, 2024. To aid our analysis, we solicited and received written views from HHS and DEA on all three questions and from the State Department on the third question. *See* Memorandum for the Office of Legal Counsel from DEA (Jan. 30, 2024) ("DEA Response"); Memorandum for Gillian E. Metzger, Deputy Assistant Attorney General, Office of Legal Counsel, from Samuel R. Bagenstos, General Counsel, HHS, *Re: OLC's Request for Views on Issues Related to the Scheduling of Marijuana Under the Controlled Substances Act* (Jan. 29, 2024) ("HHS Response"); Single Convention Requirements for Cannabis and Scheduling Under the Controlled Substances Act (Feb. 12, 2024) ("State Response").

include the Secretary's evaluation of a drug's currently accepted medical use or any scientific and medical considerations involved in that evaluation?

(3) Does the CSA, including the requirement that the Attorney General control drugs "under the schedule he deems most appropriate to carry out" the United States' "obligations under international treaties, conventions, or protocols in effect on October 27, 1970," *id.* § 811(d)(1), require DEA to place marijuana in either Schedule I or Schedule II to comply with the Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407 ("Single Convention")?

As explained in more detail below, we conclude, first, that DEA's current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS's two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by FDA and would not satisfy DEA's five-part test.

Second, we conclude that HHS's overall CAMU recommendation is not binding on DEA. We also conclude that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.

Third, we conclude that neither the Single Convention nor the CSA requires DEA to place marijuana in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific controls that follow from a drug's placement on a particular schedule. As a result, we conclude that DEA may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional controls pursuant to the CSA's regulatory authorities.

I.

A.

Sections 811 and 812 of the CSA set forth the procedures and standards the Attorney General (and thus DEA) must follow to add a drug to a schedule, transfer a drug between schedules, or remove a drug from the schedules of control. Section 811(a) authorizes the Attorney General to add or transfer a drug to, or remove a drug from, a schedule by issuing a rule "made on the record after opportunity for a hearing" pursuant to the formal rulemaking procedures of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 553(c), 556, 557. In promulgating such rules, the Attorney General is required to make particular findings, based on substantial evidence, that correspond to the schedule in which the drug is to be placed. 21 U.S.C. §§ 811(a)(1)(A)–(B), 812(b); *see also id.* § 811(b); 5 U.S.C. § 556(d).

Section 812(b) lists the findings the Attorney General must make to place a drug in a particular schedule, with the findings varying by schedule. For example, the Attorney General may place a drug in Schedule I only if the Attorney General finds that the drug "has a high potential for abuse," 21 U.S.C. § 812(b)(1)(A); "has no currently accepted medical use in treatment in the United States," *id.* § 812(b)(1)(B); and "[t]here is a lack of accepted safety for use" of the drug "under medical supervision," *id.* § 812(b)(1)(C). To place drugs in other schedules, the Attorney General must similarly make three findings, except that drugs on the other schedules must have a CAMU (or, in the case of Schedule II drugs, a CAMU with "severe restrictions"). *Id.* § 812(b)(2)(B), (b)(3)(B), (b)(4)(B), (b)(5)(B). Drugs are to be placed in less restrictive schedules as their potential for abuse and likelihood of leading to physiological or physical dependence declines. *Id.* § 812(b)(2)–(5). In the course of making these findings, section 811(c) requires the Attorney General to consider eight medical, scientific, and law-enforcement factors regarding the drug:

> (1) Its actual or relative potential for abuse.
>
> (2) Scientific evidence of its pharmacological effect, if known.

> (3) The state of current scientific knowledge regarding the drug or other substance.
>
> (4) Its history and current pattern of abuse.
>
> (5) The scope, duration, and significance of abuse.
>
> (6) What, if any, risk there is to the public health.
>
> (7) Its psychic or physiological dependence liability.
>
> (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Id. § 811(c).

Although section 811 provides that the Attorney General will issue the final rule to schedule a drug, *see id.* § 811(a), the CSA also assigns a significant role in scheduling decisions to the Secretary. Section 811(b) requires the Attorney General, before initiating a rulemaking proceeding to schedule or reschedule a drug, to request both a scientific and medical evaluation of the drug from the Secretary and the Secretary's recommendation as to the schedule, if any, in which the drug should be placed. The Secretary's recommendations "shall be binding on the Attorney General as to such scientific and medical matters" and the Attorney General is prohibited from controlling a drug if the Secretary recommends that it not be controlled. *Id.* § 811(b). After receiving the views of the Secretary, the Attorney General must initiate rulemaking proceedings if there is sufficient evidence to do so. *See id.*

The legislative history of section 811(b) indicates that its purpose was to place scientific and medical judgments in the hands of the Secretary. The report of the House Committee on Interstate and Foreign Commerce explains that "[c]onsiderable controversy arose" during the drafting process over the scheduling provisions of the bill, in particular "with respect to the proper role of the Attorney General and the Secretary of Health, Education, and Welfare [('HEW')][4] in making determinations concerning which drugs should be controlled." H.R. Rep. No. 91-1444, at 22 (1970).

[4] In 1979, Congress created the Department of Education and changed the name of the Department of Health, Education, and Welfare to the Department of Health and Human Services. Department of Education Organization Act, Pub. L. No. 96-88, §§ 201, 509, 93 Stat. 668, 671, 695 (1979).

This controversy appears to have stemmed from the fact that the version of the CSA that passed the Senate vested full decisionmaking authority regarding scheduling in the Attorney General alone and required only that the Attorney General obtain the "advice" of the Secretary in connection with scheduling decisions. S. 3246, 91st Cong. § 201(a) (1970); *see* 116 Cong. Rec. 1671, 1672 (1970). During the House's consideration of the bill, Members of Congress, HEW officials, and scientific and medical professionals raised concerns over the dominant role the Senate bill assigned to the Attorney General, arguing that scheduling decisions largely require scientific and medical expertise and that HEW, not the Department of Justice, had this expertise. *See, e.g.*, *Drug Abuse Control Amendments—1970: Hearings Before the Subcomm. on Pub. Health & Welfare of the H. Comm. on Interstate & Foreign Commerce*, 91st Cong. 102–04, 194–95, 199, 550, 557, 580–81 (1970) ("House Hearing").

Reflecting these concerns, the House version of the bill, H.R. 18583, 91st Cong. (1970), made several changes to what is now 21 U.S.C. § 811(b) that expanded the role of the Secretary and eventually became law. The requirement that the Attorney General obtain "advice" was changed to an obligation to obtain "recommendations" that bound the Attorney General with respect to scientific and medical matters. H.R. 18583, § 201(b). The House bill also added a requirement that the Secretary give a recommendation regarding the schedule in which the drug should be placed and provided that the Attorney General could not control a drug that the Secretary recommended not be controlled. *Id.*

B.

As noted above, Congress classified marijuana as a Schedule I drug when it enacted the CSA in 1970. *See* 21 U.S.C. § 812(c). Shortly thereafter, several organizations petitioned to move marijuana from Schedule I to Schedule V. *See* 37 Fed. Reg. 18,097 (Sept. 7, 1972). The petition was denied three times, but each time on review the United States Court of Appeals for the District of Columbia Circuit remanded for further analysis. *See Nat'l Org. for the Reform of Marijuana Laws v. Ingersoll*, 497 F.2d 654, 661 (D.C. Cir. 1974); *Nat'l Org. for the Reform of Marijuana Laws v. DEA*, 559 F.2d 735, 757 (D.C. Cir. 1977) ("*NORML II*"); *Nat'l Org. for the Reform of Marijuana Laws v. DEA*, No. 79-1660, 1980 U.S. App. LEXIS 13099, at *1 (D.C. Cir. Oct. 16, 1980) (per curiam).

After the third remand, DEA denied the rescheduling petition once more, concluding that marijuana did not have a CAMU. *See* 54 Fed. Reg. 53,767, 53,767, 53,783–84 (Dec. 29, 1989). In reaching that conclusion, DEA relied on an eight-part test for determining whether a drug had a CAMU that included the following three factors: whether the drug was generally available; whether its use was generally recognized in various medical reference works; and whether its use was recognized by "a substantial segment of the medical practitioners in the United States." *Id.* at 53,783. As before, the petitioners sought review and the D.C. Circuit remanded the case to DEA, concluding that these three factors were arbitrary and capricious because they would be "logically impossible" for drugs in Schedule I to satisfy. *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937, 940 (D.C. Cir. 1991) ("*ACT I*"). But the court held that DEA's interpretation of the statutory phrase "currently accepted medical use" was "in the main acceptable," and rejected petitioners' principal argument that DEA's interpretation unreasonably relied upon "the absence of demonstrated scientific evidence that the drug is medically useful and safe." *Id.* at 937, 939. In particular, the court noted that the petitioners had presented only "anecdotal evidence" that "a number of physicians believe marijuana is medically useful." *Id.* at 939.

On remand a fourth time, DEA again denied the petition, again finding that marijuana did not have a CAMU. 57 Fed. Reg. at 10,499. DEA stated that a drug would have a CAMU if it had been approved by FDA under its "New Drug Application" process or if the drug met the criteria to be recognized by FDA as "Generally Recognized As Safe and Effective." *Id.* at 10,503 (citing 21 U.S.C. §§ 321(p), 355). In addition, DEA concluded that a drug would have a CAMU if it satisfied a new, five-part test (a revised version of DEA's previous eight-part test that the D.C. Circuit considered in *ACT I*). *Id.* at 10,504. Under DEA's new test, a drug has a CAMU if the following elements are satisfied:

(1) the drug's chemistry is known and reproducible;

(2) there are adequate safety studies;

(3) there are adequate and well-controlled studies proving efficacy;

(4) the drug is accepted by qualified experts; and

(5) scientific evidence about the drug is widely available.

Id. at 10,503–06. All five parts were based on the "core FDCA standards for acceptance of drugs for medical use," and four were expressly derived from the FDCA or FDA regulations setting forth requirements that a drug must meet before receiving FDA approval. *Id.* at 10,504–05 (citing 21 U.S.C. §§ 321(p), (w), 355(d); and 21 C.F.R. §§ 314.103(c)(3), 314.50(d)(1), 314.125(b), 314.126). DEA concluded that marijuana did not meet any of these criteria and accordingly denied the request to remove marijuana from Schedule I. *Id.* at 10,507–08.

This time the D.C. Circuit upheld DEA's decision. *See All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994) ("*ACT II*"). It rejected the petitioners' "central claim" that DEA's order rested on an "unreasonable interpretation of the statute." *Id.* The court noted that it had already concluded in *ACT I* that DEA's interpretation of the CSA was generally reasonable, and it refused to reconsider that determination. *Id.* at 1134. It further reasoned that none of the criteria in DEA's new five-part test were "impossible for a Schedule I drug to meet" and that DEA had "corrected the flaws [the court] identified in" *ACT I*. *Id.* at 1135.

Since *ACT II*, DEA has denied several petitions that sought rescheduling of marijuana after applying its five-part test and concluding that marijuana did not have a CAMU. *See, e.g.*, 66 Fed. Reg. 20,038, 20,038 (Apr. 18, 2001); 76 Fed. Reg. 40,552, 40,552 (July 8, 2011); 81 Fed. Reg. 53,688, 53,688 (Aug. 12, 2016); 81 Fed. Reg. 53,767, 53,767 (Aug. 12, 2016). Efforts to challenge these denials in court have proven unsuccessful. *See Ams. for Safe Access v. DEA*, 706 F.3d 438, 450 (D.C. Cir. 2013); *Krumm v. DEA*, 739 F. App'x 655 (D.C. Cir. 2018). In recent years, however, several jurists have raised serious concerns about DEA's conclusion that marijuana does not have a CAMU. *See United States v. Green*, 222 F. Supp. 3d 267, 275 (W.D.N.Y. 2016); *United States v. Amalfi*, 47 F.4th 114, 125 (2d Cir. 2022); *Sisley v. DEA*, 11 F.4th 1029, 1036 (9th Cir. 2021) (Watford, J., concurring).

C.

Since 1996, 38 States, the District of Columbia, and four federal territories have legalized the use of medical marijuana. *See* HHS Part 1 Analysis Memo at 4. These laws typically allow the cultivation, sale, and use of marijuana by patients (or their caregivers) whose health care practitioners have recommended that they use marijuana to treat certain, specified

conditions. *See, e.g.*, Ohio Rev. Code §§ 3796.01(A)(6)(a)–(v), 3796.08(A); N.Y. Cannabis Law §§ 3(18), 30, 31; N.M. Stat. §§ 26-2B-3(F)(1)–(23), 26-2B-3(N), 26-2B-4(A). Conditions can be added to, or removed from, the list of illnesses that may be treated with marijuana, often by (or at the recommendation of) a state's public health authorities or special boards convened to consider such matters. *See, e.g.*, Conn. Gen. Stat. § 21a-408*l*(a), (c); 410 Ill. Comp. Stat. §§ 130/10(h)(2), 130/45; Or. Admin. Rule 333-008-0090. In each fiscal year since 2015, Congress has also adopted an appropriations rider that prohibits the Department of Justice from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana. *E.g.*, Consolidated Appropriations Act, 2024, Pub. L. No. 118-42, § 531, 138 Stat. 25; Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 531, 136 Stat. 4459, 4561 (2022); *see* Cong. Rsch. Serv., R44782, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap* at 26 & n.159 (updated Apr. 7, 2022) (collecting laws).

On October 6, 2022, as noted above, President Biden asked the Secretary and the Attorney General to review how marijuana is scheduled under federal law. As part of its analysis in response to this request, HHS considered whether DEA's test for determining if a drug has a CAMU was consistent with the text of the CSA. HHS Response at 5–6. HHS agreed that if a drug met the requirements for FDA approval or DEA's five-part test, the drug would have a CAMU. *Id.* at 8. But it concluded that it would be inconsistent with the text and purpose of the CSA for those standards to be the "sole basis for determining whether a substance has a [CAMU]." *Id.* at 7.

HHS's analysis instead relied on an additional, two-part inquiry for considering whether a drug has a CAMU. Part 1 of HHS's inquiry focuses on the extent and nature of medical use. It asks whether there is "widespread current experience with medical use of the substance in the United States by licensed health care practitioners . . . operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine." HHS Part 1 Analysis Memo at 1. HHS further identifies several factors to consider in undertaking this analysis, none being dispositive on its own—specifically, (1) "[w]hether a substantial number of licensed health care practitioners

have gained clinical experience with at least one specific medical use of the substance under existing and implemented state-authorized programs," *id.* at 3; (2) "[w]hether a substantial number of entities that regulate the practice of medicine recognize at least one specific medical use of the substance," *id.*; and (3) "[w]hether licensed health care practitioners' clinical experience with the medical use of the substance is of sufficient extent and duration to help evaluate potential clinical uses and longer term toxicities and potential harms of the substance when used under medical supervision," *id.* at 5.

Part 2 of HHS's test focuses on the scientific basis for any identified medical use. It asks whether there is "some credible scientific support for at least one medical use of the substance for which Part 1 is met." *Id.* at 2. According to HHS, although again not dispositive, factors that count in favor of the conclusion that some credible scientific support exists include (1) whether "favorable clinical studies of the medical use" of the drug, although not FDA approval-level studies, "have been published in peer-reviewed journals" and (2) whether "[q]ualified expert organizations (e.g., academic or professional societies, government agencies) have opined in favor of the medical use or provided guidance to practitioners on the medical use." Ctr. for Drug Evaluation & Rsch., FDA, *Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act* at 4 (Aug. 28, 2023) ("HHS Part 2 Analysis Memo"). By contrast, factors weighing against the conclusion that such credible scientific support exists include (1) whether "data or information indicates that medical use of the substance poses unacceptably high safety risks for the likely patient population, e.g., due to toxicity concerns"; (2) whether "clinical studies with negative efficacy findings for the medical use have been published in peer reviewed journals"; and (3) whether "qualified expert organizations (e.g., academic or professional societies, government agencies) have recommended against the medical use of the substance." *Id.* at 4–5.

Applying this two-part inquiry, HHS concluded that marijuana has a CAMU. *Id.* It found that Part 1 of its inquiry was satisfied because more than 30,000 licensed health care practitioners across 43 jurisdictions are authorized to recommend the use of marijuana for more than six million registered patients for at least 15 medical conditions. HHS Part 1 Analysis Memo at 1. HHS also found that Part 2 of its inquiry was satisfied. *See*

HHS Part 2 Analysis Memo at 7. Although noting that no professional medical organization currently recommends use of marijuana (and that one recommends against its use), HHS concluded after reviewing several studies that there was some credible scientific support that marijuana could be used to effectively treat pain, anorexia, and nausea and vomiting and that using medical marijuana to treat these conditions did not pose "unacceptably high safety risks." *Id.* at 7. Consistent with this conclusion, and in light of other findings it made, HHS recommended to DEA that marijuana be placed in Schedule III of the CSA.

II.

As discussed above, DEA currently concludes that a drug has a CAMU only if FDA has approved the drug under the FDCA or the drug meets DEA's five-part test. 57 Fed. Reg. at 10,505–06. HHS agrees with DEA that FDA approval and DEA's five-part test are sufficient to establish that a drug has a CAMU, *see* HHS Response at 8, and we also agree. To receive FDA approval, a drug must satisfy "rigorous testing and safety reviews" showing that the drug is "both safe and effective." *Sadoz Inc. v. Becerra*, 57 F.4th 272, 282 (D.C. Cir. 2023). And the entire purpose of FDA's rigorous approval process is to identify drugs that can be safely and effectively used to treat medical conditions. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133–34 (2000). It would thus make no sense to keep a drug that has met—or could meet—FDA's standards on Schedule I, which would prevent the drug from being used to treat medical conditions. *See* 21 U.S.C. §§ 829, 841–43.

HHS argues, however, that DEA's approach to CAMU is impermissibly narrow and that HHS's two-part inquiry is a permissible way to establish that a drug has a CAMU. You have asked whether, if a drug satisfies the two-part inquiry employed by HHS, that establishes that the drug has a CAMU regardless of whether the drug has been approved by FDA or satisfies DEA's five-part test. For the reasons that follow, we agree with HHS and conclude that limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA's five-part test is an impermissibly narrow interpretation of section 812(b) and that satisfying HHS's two-part inquiry is sufficient to establish that a drug has a CAMU.

A.

Section 812(b) requires the Attorney General (and thus DEA), in making scheduling decisions under the CSA, to determine whether a drug has a "currently accepted medical use in treatment in the United States." It is hard to square DEA's exclusive reliance on FDA approval and its five-part test with this language.

To begin, DEA's approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard. At the time the CSA was adopted (and as is still true today) the word "accepted" meant "widely used or found" or "generally approved." *Accepted*, Webster's Third New International Dictionary 11 (1971); *see also Accepted*, The American Heritage Dictionary of the English Language 8 (1970) ("Generally approved, believed, or recognized."); *Accepted*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/accepted (last visited Apr. 2, 2024) (defining "accepted" to mean "regarded favorably" or "generally approved or used"). And the focus on "medical use" suggests that the relevant inquiry is whether the medical community has accepted that a drug has a "use in treatment." 21 U.S.C. § 812(b)(1)(B).

Any examination of whether the medical community "accept[s]" that a drug has a "use in treatment," *id.*, naturally requires an examination of what licensed health care practitioners are actually doing. Practitioners treat patients, after all, and their treatment decisions and clinical experience with a drug (where such experience exists) provide important evidence in determining whether a medical use is accepted. Moreover, an understanding of what the medical community accepts would also naturally require consideration of the views of the principal regulators of the medical profession: state entities that license and police healthcare practitioners. As the Supreme Court has noted, the CSA "presume[s] and rel[ies] upon a functioning medical profession regulated under the States' police powers." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).

But neither FDA approval nor DEA's five-part test examines whether health care practitioners are actually using a drug to treat a condition or whether the entities regulating those practitioners allow the drug to be so used. Instead, FDA approval and DEA's five-part test rely exclusively on certain scientific evidence and the views of some experts and FDA. Simp-

ly put, ignoring widespread clinical experience with a drug that is sanctioned by state medical licensing regulators when evaluating whether a drug has a CAMU is at odds with the plain meaning of section 812(b).[5]

Limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA's five-part test also conflicts with the text of section 812(b) by erroneously equating identification of an "accepted" medical use under the CSA with the "approval," or potential approvability, of the drug under the FDCA. Under the CSA, a substance can only be placed on Schedule I if it lacks *both* a "currently accepted medical use in treatment in the United States" *and* an "accepted safety for use . . . under medical supervision." 21 U.S.C. § 812(b)(1)(B), (C). By contrast, "the FDCA does not even mention the term 'medical use,'" *Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir. 1987), and under the FDCA approval can be denied *either* because the drug is unsafe *or* because it is ineffective, *see* 21 U.S.C. § 355(d)(2), (5). FDA may also deny approval for several other reasons that have nothing to do with medical use, including that the application did not contain the necessary patent information, *see id.* § 355(d)(6), or that the methods used to manufacture, process, and pack the drug "are inadequate to preserve its identity, strength, quality, and purity," *id.* § 355(d)(3).

Moreover, other CSA provisions confirm that a drug having a CAMU is distinct from it being approved (or approvable) by FDA. Among other things, the CSA elsewhere repeatedly refers to, and in some places explicitly relies on, the FDCA. As an example, 21 U.S.C. § 829 prohibits the dispensing of "prescription drug[s] as determined under the [FDCA]" that are controlled under Schedules II through IV without a prescription from a practitioner, subject to certain exceptions. *See also, e.g.*, *id.* §§ 811(g)(1), 825(e). Congress's decision to explicitly invoke the FDCA's standards with respect to some parts of the CSA, but not with respect to whether a drug has a CAMU, strongly suggests that it did not mean to equate CAMU with the standards necessary for FDA approval.

[5] The First Circuit's decision in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), is not to the contrary. *Grinspoon* rejected the argument that Congress meant to privilege the views of "certain members of the medical community" in determining if a drug has a CAMU. *Id.* at 892. The court did not consider, however, the broader understanding of the relevant inquiry that we offer here—i.e., whether the medical community as a whole, including practitioners and regulators (among others), has "accepted" that a drug has a "medical use in treatment." 21 U.S.C. § 812(b)(1)(B).

Amendments to the CSA reinforce this conclusion. Congress added the "emergency scheduling" provision to the CSA in 1984. Pub. L. No. 98-473, § 508, 98 Stat. 1837, 2071–72 (1984) (codified as amended at 21 U.S.C. § 811(h)). That provision allows the Attorney General to place certain substances in Schedule I on a temporary basis without following the normal scheduling criteria if "necessary to avoid an imminent hazard to the public safety." 21 U.S.C. § 811(h). But this authority does not apply where an "exemption or approval is in effect for the [drug] under section 505" of the FDCA—i.e., where FDA allows the drug to be marketed in interstate commerce. *See id.*; *see also* Controlled Substances Analogue Enforcement Act of 1986, Pub. L. No. 99-570, tit. I, subtit. E, 100 Stat. 3207, 3207-13 to -14 (codified as amended at 21 U.S.C. § 801(32)) (exempting drugs that have been approved by FDA from the definition of controlled substance analogue). As the First Circuit has observed, these provisions demonstrate that "absolute reliance on the absence of FDA approval" outside of these limited contexts "would be inappropriate and, indeed, contrary to the intent of Congress in enacting the CSA." *Grinspoon*, 828 F.2d at 890.

We recognize that our conclusion that DEA cannot rely exclusively on FDA approval or its five-part test in determining whether a drug has a CAMU is in some tension with the D.C. Circuit's decisions in *ACT I* and *ACT II*. The record in those cases, however, was materially different from the one contemplated by HHS's two-part inquiry: the petitioners in *ACT I* and *ACT II* had shown that, at most, a "number of physicians believe[d] that marijuana is medically useful"—evidence that the court twice said was "anecdotal." *ACT I*, 930 F.2d at 939; *see also id.* (describing petitioner's evidence as "largely anecdotal"). Indeed, although the court noted that it "ha[d] no grounds" on the record before it "to dispute [DEA's] premise that without much more complete scientific data American physicians will not 'accept' marijuana," it further observed that DEA's conclusion would be "more vulnerable" if "virtually all doctors in the United States were vociferous in their espousal of marijuana for medical treatment—notwithstanding scientific uncertainties." *Id.*; *see also ACT II*, 15 F.3d at 1134–35 (holding that DEA's interpretation of "currently accepted medical use" was reasonable on law of the case grounds).

In other words, neither *ACT I* nor *ACT II* assessed DEA's approach in the circumstance envisioned by HHS's two-part inquiry—where there is

"widespread current experience with medical use of" a Schedule I drug in the United States by licensed health care practitioners "operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine." HHS Part 1 Analysis Memo at 1. To the contrary, the D.C. Circuit suggested that such circumstances might never occur, as one of its reasons for rejecting DEA's original eight-part test was that it "appear[ed] impossible" for a Schedule I drug to meet the requirement that there be "[r]ecognition and use of the [drug] by a substantial segment of the medical practitioners in the United States." *ACT I*, 930 F.2d at 938, 940. Yet with respect to at least one drug—marijuana—subsequent events have shown that a drug can be in Schedule I but still be recommended for medical use by a large number of medical practitioners in the United States. And for the reasons we have explained, when these circumstances exist, the plain text of section 812 mandates that they be taken into account when determining whether a drug has a CAMU.

B.

Having explained why DEA's construction of the phrase "currently accepted medical use in treatment in the United States" is impermissibly narrow, we turn to why HHS's two-part inquiry is sufficient to determine whether a drug has a CAMU.

1.

Part II.A explained that, to determine if a drug has a CAMU, section 812(b) requires an analysis of whether, at the present time, the medical community widely understands that a drug has a "use in treatment in the United States." Although there is no single right answer as to *how* specifically DEA should make this determination, the text of the CSA establishes certain basic parameters to guide the inquiry.

As an initial matter, the definitions discussed above indicate that "accepted" means that something is "*widely* used or found" or "*generally* approved." *Accepted*, Webster's Third New International Dictionary 11 (emphasis added). It therefore follows from the word's plain meaning that "anecdotal evidence" that a "number of physicians believe that [a drug] is medically useful" is not enough to show that the medical community has

accepted that a drug has a use in treatment in the United States. *ACT I*, 930 F.2d at 939. At the same time, however, "accepted" does not require universal consensus. Rather, it is sufficient if there is a widespread understanding in the medical community that a drug has a use in treatment.

Relatedly, nothing in the text of the CSA suggests that establishing that a drug has a CAMU requires the medical community to believe that the drug is the best way to treat a condition. So long as there is widespread understanding in the medical community that a drug is a permissible and reasonable way to treat a condition, it has a CAMU. That reflects a basic reality about the medical profession: that "in medicine there is often a range of reasonable treatments[.]" *Young v. United States*, 942 F.3d 349, 352 (7th Cir. 2019).

Moreover, the medical community is not a monolith: It contains individuals and entities with a range of expertise and experiences, including licensed health care practitioners who specialize in certain areas of medicine, generalists with broader expertise, researchers, and regulators. In assessing the views of the medical community, section 812(b)(1)(B)'s emphasis on a "medical use in treatment" indicates that the views of all these constituencies are not equally important in every case. Instead, to determine whether the medical community understands using a particular drug to be within the range of reasonable treatment options, it is the views and practices of the health care practitioners who actually treat a given condition, as well as the regulators charged with enforcing applicable norms of practice, that are often especially relevant.

Finally, we believe a CAMU test must include consideration of the scientific evidence that supports the relevant medical use. This follows from section 811(c)'s requirement that the Attorney General "shall consider" eight factors in making the CAMU determination and other findings under section 812(b), some number of which inherently require consideration of scientific evidence. Although it is unclear exactly how the eight factors listed in section 811(c) correlate to the findings required by section 812(b), it is plain that at least two of those factors—the "scientific evidence of [the drug's] pharmacological effect, if known" and the "state of current scientific knowledge regarding the drug," 21 U.S.C. § 811(c)(2), (3)—bear on whether a drug has a currently accepted medical use, and that those factors necessarily require evaluation of scientific evidence. In addition, the requirement to consider "[w]hat, if any, risk there is to the

public health" and the drug's "psychic or physiological dependence liability," *id.* § 811(c)(6), (7), further suggests that an assessment of the available science is an integral part of a CAMU determination. Reviewing the available scientific evidence as part of the CAMU analysis is also consistent with the common-sense intuition that there is an inherent connection between whether the medical community has "accepted" a drug for "use in treatment," *id.* § 812(b)(1)(B), and the scientific evidence supporting that conclusion. We generally would not expect the medical community to understand that it is reasonable to use a drug to treat a condition unless (as HHS suggests) there is at least some scientific evidence in support of that conclusion—evidence demonstrating, for example, that the drug was effective in treating the condition or does not create unacceptably high safety risks. HHS Part 2 Analysis Memo at 4–5.

2.

We conclude that HHS's two-part inquiry falls within the basic parameters the CSA provides for establishing that a drug has a CAMU.

Part 1 of HHS's test requires an assessment of whether health care practitioners are recommending that patients use a drug to treat a medical condition and whether they are doing so in accordance with guidelines issued by entities that regulate the practice of medicine. This approach is consistent with our view that determining whether a drug has a CAMU requires assessing whether there is a widespread understanding in the medical community that using the drug to treat a condition falls within the range of reasonable treatment options. In particular, the actual recommendations of practitioners made under applicable regulatory guidelines constitute strong evidence of whether the medical community understands a drug to be a reasonable treatment option.

The three non-dispositive factors HHS includes in its Part 1 analysis further demonstrate why its test is sufficient. Two of HHS's factors look, respectively, at whether a "substantial number of licensed health care practitioners" have gained clinical experience with a drug under a state-authorized program and whether a "substantial number" of entities that regulate the practice of medicine have authorized the use of a drug for medical purposes. *See* HHS Part 1 Analysis Memo at 3. In our view, these inquiries provide good evidence of whether there is widespread agreement within the medical community that using the drug would be a reasonable

treatment option. Similarly, it is more likely that the medical community would widely understand that a drug represents a reasonable treatment option if HHS's third factor is present—i.e., that practitioners' clinical experience with the drug is of a "sufficient extent and duration" to help evaluate whether there are "potential clinical uses," "longer-term toxicities," and "potential harms." *Id.* at 5.

Moreover, Part 2 of HHS's test adequately takes the available scientific evidence into account by asking whether there is some credible scientific support for a least one of the medical uses for which the Part 1 test is met and then providing guidance as to what counts as "credible" scientific support. *See* HHS Part 2 Analysis Memo at 4 (identifying "favorable clinical studies" published in peer-reviewed journals as cutting in favor of the conclusion that the drug has a CAMU); *id.* (identifying data or information that "indicate[s] that medical use of the [drug] is associated with unacceptably high safety risks for the likely patient population" because of "toxicity concerns" as cutting against the conclusion that the drug has a CAMU). Neither section 811(c) nor section 812(b) requires a particular threshold of scientific support to conclude that a drug has a CAMU, and we believe that Part 2's requirement of some credible scientific support is sufficient in a context where health care practitioners have extensive experience with a drug and medical regulators have sanctioned the drug's use. Such clinical experience and regulatory sanction provide alternative sources of information about a drug, thereby making it reasonable not to require the high level of scientific support that might be demanded before a new and untried drug is determined to have a CAMU.

DEA's main concern with HHS's two-part inquiry is that it places too much emphasis on state regulatory decisions. Specifically, DEA suggests that HHS's emphasis on states is "misplaced" because, in DEA's view, the processes states follow for enacting legislation "are generally less rigorous than the requirements placed on federal agencies when they act pursuant to the APA." DEA Response at 11. But there is nothing in the text of the CSA that would warrant categorically discounting state practice in this fashion, particularly since doing so would be inconsistent with both the role of states as the central regulators of medical practice, *see Oregon*, 546 U.S. at 270, 274–75, and the fact that they are afforded "great leeway" in adopting measures to "protect public health and safety," *Mackey v. Montrym*, 443 U.S. 1, 17 (1979). Indeed, Congress has already

recognized the importance of states' views on whether marijuana in particular may be used to treat medical conditions by annually adopting an appropriations rider that prohibits the Department of Justice from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana. *See supra* Part I.C.

In addition, states do often look to scientific and medical judgment in regulating medical marijuana. States typically only allow medical practitioners to recommend medical marijuana to treat specific conditions. *See, e.g.*, Ohio Rev. Code § 3796.01(A)(6)(a)–(v); N.Y. Cannabis Law § 3(18). In some states, practitioners may only recommend the use of medical marijuana after determining that the patient suffers from one of those conditions and that the "potential benefits of the palliative use of marijuana would likely outweigh the health risks of such use." *E.g.*, Conn. Gen. Stat. § 21a-408c(a); *see also* Fla. Stat. § 381.986(4). Several states have also established processes through which experts can recommend additions to, or removals from, the list of conditions that marijuana may be used to treat, *see, e.g.*, Conn. Gen. Stat. § 21a-408*l*(a), (c)(1), (d); Or. Admin. Rule 333-008-0090(3)(e), (4)(a)—indeed, HHS has informed us that 17 jurisdictions have added conditions that may be treated with marijuana using such processes, *see* HHS Part 1 Analysis Memo at 4. In short, it is simply not the case that state practice concerning medical marijuana is completely divorced from scientific and medical assessment.

III.

As discussed above, the CSA authorizes the Attorney General to place drugs in particular schedules if, after a formal rulemaking, the Attorney General makes certain findings. A particularly important finding is whether a drug has a CAMU, as the Attorney General may only keep or place a drug in Schedule I if it lacks a CAMU. Before initiating a rulemaking proceeding to schedule or reschedule a drug, however, the Attorney General is required to request recommendations from the Secretary that must include whether the drug has a CAMU. *See* 21 U.S.C. § 811(b). The CSA further makes these recommendations binding "as to" certain "scientific and medical matters." *Id.*

Since HHS has recommended that marijuana has a CAMU, you have asked about the extent to which the "scientific and medical matters" that

are binding on the Attorney General, and thus DEA, include HHS's CAMU recommendation or any scientific and medical determinations underlying that recommendation. For the reasons that follow, we conclude, first, that HHS's overall CAMU recommendation is not binding on DEA. Second, we conclude that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.

A.

We first explain why HHS's overall CAMU recommendation does not bind DEA, starting with the two CSA provisions that govern the CAMU determination. Section 811(a) authorizes the Attorney General to schedule or reschedule a drug if the Attorney General makes certain findings "on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by [the APA]." Section 812(b) then lays out the relevant findings the Attorney General must make to schedule a drug, including whether the drug has a CAMU.

Taken together, these two provisions commit exclusively to the Attorney General the ultimate responsibility for making the findings required to schedule a drug, including a CAMU finding, and neither mentions the Secretary at all. Instead, the role of the Secretary is addressed in a separate provision of the CSA, section 811(b), which reads as follows:

> The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The

> recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

This provision makes clear that the Secretary plays a crucial role in the scheduling process. It expressly directs the Attorney General to obtain a scheduling recommendation from the Secretary before initiating the scheduling process and to treat as binding certain "scientific or medical matters." *Id.*[6] But section 811(b) does not so much as mention the Secretary's

[6] In two recent rulemakings, DEA has stated that HHS's scientific and medical recommendations only bind DEA with respect to factors (1), (4), and (5) of section 811(c). See 86 Fed. Reg. 29,506, 29,507–08 (June 2, 2021); 86 Fed. Reg. 27,803, 27,805 (May 24, 2021). This view appears to be based on a contrast in section 811(b)'s text: it directs the Secretary to "consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of [section 811(c)]," and "any scientific or medical considerations involved in paragraphs (1), (4), and (5) of [section 811(c)]," with the Secretary's recommendations being "binding . . . as to such scientific and medical matters." But section 811(b) highlights the "scientific and medical considerations" in factors (1), (4), and (5) not because HHS should consider the science and medicine underlying only those factors, but rather because those factors all relate to a drug's abuse potential, the analysis of which Congress understood as resting primarily on law enforcement considerations. See H.R. Rep. No. 91-1444, at 33–36; House Hearing at 718. By comparison, there is no need to direct HHS to consider the "scientific or medical considerations" involved with factors (2), (3), (6), (7), and (8) since those factors involve inquiries that are predominantly, if not entirely, scientific and medical in nature. We thus think it plain that HHS's recommendations with respect to "scientific and medical matters" are binding for all eight factors listed in section 811(c). *See* H.R. Rep. 91-1444, at 33; *see also id.* at 22–23 ("*[A]ll* scientific and

CAMU recommendation. Instead, section 811(b) expressly identifies a different circumstance in which the Secretary's recommendation concerning an ultimate scheduling determination is dispositive: when the Secretary recommends against controlling a drug. This fact—that section 811(b) identifies a separate scheduling recommendation as binding—makes its silence on the Secretary's CAMU recommendation all the more conspicuous.

Moreover, we do not believe the Secretary's authority to bind the Attorney General with respect to "scientific and medical matters" encompasses a CAMU determination, because such a determination involves judgments that are neither wholly scientific nor wholly medical. For example, as the discussion in Part II indicates, assessing whether a drug has a CAMU may involve, in part, determining whether the extent of medical use present is sufficient to qualify as "accepted" within the medical community. 21 U.S.C. § 812(b)(1)(B). This inquiry is more akin to the application of a legal standard to a set of facts than a judgment necessarily requiring medical or scientific expertise, as it could turn (at least in part) on reasoning or facts that are neither scientific nor medical in nature, such as determining how many states have authorized use of a drug in treating a medical condition. *Cf., e.g.*, *United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005) (conclusions that are the "product of reasoning processes familiar to the average person in everyday life" do not require specialized expertise); *accord United States v. Vega*, 813 F.3d 386, 394–95 (1st Cir. 2016) (conclusions based on "logic and pattern recognition" do not require specialized expertise). Because a CAMU determination can include elements that fall outside the substantive scope of HHS's authority to bind DEA, HHS's overall determination that a substance has (or lacks) a CAMU cannot be binding.

B.

We next explain why the scientific and medical determinations underlying HHS's overall CAMU recommendations bind DEA, although only until the initiation of formal rulemaking, and why DEA is nonetheless obligated to accord the findings significant deference thereafter.

medical determinations [will be] made by the Secretary of Health, Education, and Welfare[.]" (emphasis added)).

As a threshold matter, the text and legislative history of section 811(b) demonstrate that the "scientific and medical matters" binding on the Attorney General include the scientific and medical determinations that underlie the Secretary's CAMU recommendation. *See* H.R. Rep. No. 91-1444, at 33; HHS Response at 10; DEA Response at 16. For example, whether some credible scientific support exists for a particular widespread clinical use, *see supra* Part I.C, is undoubtedly relevant to a CAMU finding—and undoubtedly a "scientific and medical matter."

The more difficult question, however, is whether HHS's scientific and medical determinations remain binding throughout the scheduling process—a question on which DEA and HHS hold sharply different views. DEA argues that it "is only bound by HHS's evaluation as to scientific and medical matters . . . at the beginning of the [scheduling] process," but "[o]nce rulemaking has begun, DEA can—and must—consider material submitted during the administrative process in reaching a final scheduling determination." DEA Response at 13; *see also* 76 Fed. Reg. 77,330, 77,334–36 (Dec. 12, 2011) (adopting this position). HHS takes the opposite view, arguing that its scientific and medical recommendations bind DEA throughout the scheduling process, including the formal rulemaking. *See* HHS Response at 10–11.

The CSA is unquestionably hard to parse on this issue. It does not expressly address for what portion of the administrative proceedings HHS's determinations are binding, nor does it specify how, if at all, such determinations must be considered during the formal rulemaking proceedings. Moreover, what clues the statute does offer point in two opposing directions: On the one hand, the statute requires the Attorney General alone to make the ultimate findings required for scheduling after an on-the-record formal rulemaking, which implies that the Attorney General must consider contrary scientific or medical evidence submitted during that process. *See* 21 U.S.C. § 811(a). On the other hand, the statute makes the Secretary's scientific and medical determinations "binding" on the Attorney General without expressly limiting the binding nature of those determinations to any particular stage of the scheduling process. *See id.* § 811(b).

Although a close question, we think Congress's decision to make scheduling decisions subject to a formal rulemaking process ultimately provides the answer. Fundamentally, the proposition that HHS's determinations bind DEA for the entirety of the scheduling process cannot be

squared with the nature of the formal rulemaking that section 811(a) requires. Nothing in the CSA limits outside participants to submitting only nonscientific and nonmedical evidence at a rulemaking hearing. Given the possibility that parties may submit contrary scientific or medical evidence, construing section 811(b) to preclude DEA from considering such evidence would be inconsistent with the APA's requirement that rules issued via formal rulemaking be based "on consideration of the whole record . . . and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d); *see Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951) ("The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. This is clearly the significance of the requirement . . . [to] consider the whole record."). In short, DEA would not be making a decision based on the "whole record" and "in accordance with the reliable, probative, and substantial evidence," 5 U.S.C. § 556(d), if HHS's determinations barred DEA from considering contrary scientific or medical evidence. Two courts of appeals have suggested in dicta that they view the issue similarly. *See Grinspoon*, 828 F.2d at 890; *Reckitt & Colman, Ltd. v. Administrator, DEA*, 788 F.2d 22, 27 n.8 (D.C. Cir. 1986).

The fact that HHS's recommendations as to certain "scientific and medical matters" do not bind DEA for the entire scheduling process does not mean, however, that they are without effect. Rather, in order to give force to the statutory command that HHS's recommendations "bind[ ]" DEA, we believe HHS's scientific and medical determinations must be binding until the issuance of a notice of proposed rulemaking ("NPRM"). Up to this point, the formal rulemaking procedures required by section 811(a) are not yet in effect, *see* 21 C.F.R. §§ 1308.43(f), 1316.42(g), meaning there is no conflict between the statutory commands to consider contrary evidence in the record and accord binding effect to HHS's recommendations.

In addition, DEA may not simply cast aside HHS's scientific and medical recommendations once it initiates formal rulemaking proceedings by issuing an NPRM. The categorical use of the word "binding" in section 811(b) suggests that Congress intended HHS's scientific and medical views to at least be a very significant input in the scheduling process. And there would seem to be little reason to make the HHS's views binding at any stage in the process if DEA eventually could discard HHS's determi-

nations and review scientific and medical matters *de novo*. *Cf. Reno v. Am.-Arab Anti-Discrimination Comm.*, 525 U.S. 471, 487 (1999) (statutes should be read in a manner that "makes sense of the statutory scheme as a whole").

The legislative history of the CSA supports the view that HHS's scientific and medical determinations should remain significant throughout the rulemaking process. The House report on the CSA states that Congress intended "all scientific and medical determinations" to be "made by the Secretary," rather than the Attorney General, and nothing in the legislative history suggests that the Attorney General would be free to make *de novo* scientific and medical judgments once the formal rulemaking is underway. H.R. Rep. No. 91-1444, at 22–23. Indeed, the House report emphasized that section 811 was "not intended to authorize the Attorney General to undertake or support medical and scientific research" for the purpose of scheduling, as that research "is within the competence of [HHS]." *Id*. at 33. And considering this same legislative history, the Supreme Court noted in *Gonzales* that the CSA places "medical judgments" made under the Act in the "hands of the Secretary." 546 U.S. at 265.

We therefore conclude that, to give proper effect to HHS's scientific and medical determinations, DEA must continue to accord significant deference to those determinations even once formal rulemaking has commenced and may not undertake a *de novo* assessment of HHS's findings at any point in the rulemaking process.

IV.

The Single Convention requires parties to impose controls on the cultivation, manufacture, and distribution of various drugs, including "cannabis."[7] Among other things, parties to the Convention generally must

[7] The Convention defines "cannabis" as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated." Single Convention art. 1(1)(b). We understand the marijuana in use in the United States to fall within this definition, although the definition of cannabis under the Single Convention is slightly less inclusive than the CSA's definition of "marihuana," which includes all parts of the Cannabis sativa L. plant with certain exceptions, including mature stalks and sterilized seeds that are incapable of germination. *See* 21 U.S.C. § 802(16).

require that manufacturers, distributors, importers, and exporters of cannabis secure a license, Single Convention arts. 29–31; impose quotas on the import and manufacture of cannabis, *id.* art. 21(1); generally prohibit the unauthorized possession of cannabis, *id.* art. 33; and adopt penal provisions making violations of the controls required by the Convention punishable offenses, *id.* art. 36.

Several provisions of the CSA—including sections 801(7), 811(d)(1), 812(b), 823(a), 953(a), and 958(a)—"reflect Congress's intent to comply with the obligations imposed by the Single Convention." *Control of Papaver bracteatum*, 1 Op. O.L.C. 93, 95 (1977). Of particular relevance here, section 811(d)(1) provides:

> If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures described by subsections (a) and (b) of this section.

The Single Convention entered into force for the United States on June 24, 1967, and was thus "in effect on October 27, 1970." *Id.* Both our Office and the D.C. Circuit have interpreted section 811(d)(1) to apply to any scheduling action by the Attorney General concerning a drug covered by the Single Convention, including actions to transfer a drug between schedules. Memorandum for John E. Ingersoll, Director, Bureau of Narcotics & Dangerous Drugs, from Mary C. Lawton, Deputy Assistant Attorney General, Office of Legal Counsel, *Re: Petition to Decontrol Marihuana; Interpretation of Section 201 of the Controlled Substances Act of 1970* at 9 (Aug. 21, 1972) ("Lawton Memo"); *NORML II*, 559 F.2d at 747.

Given this, your third question asks whether the CSA or the Single Convention requires marijuana to be placed in Schedule I or Schedule II. This question is one our Office has considered before: in 1972, we concluded that the Convention requires marijuana to be placed in Schedule I or II because placing marijuana in Schedules III, IV, or V would not enable the United States to satisfy its Convention obligations. *See* Lawton Memo at 12–13. In particular, we emphasized that the "quotas on manu-

facture and importation of a substance required by the Convention could not be maintained under existing statutory authority were marihuana listed in Schedules III, IV, or V." *Id.*; *see also NORML II*, 559 F.2d at 750–51 (agreeing with the Lawton Memo that Schedule I or II was necessary to meet the United States' Single Convention obligations). In reaching this conclusion, however, we did not address an issue that both HHS and the State Department now ask us to consider: whether under the CSA the United States can comply with its Single Convention obligations by placing marijuana in Schedule III while "adopting such additional regulations as are necessary for treaty compliance." HHS Response at 13; State Response at 5–7; *see also NORML II*, 559 F.2d at 752–53 (recognizing the possibility of a similar regulatory approach but taking no position on its availability).

We think this question is a close one. For the reasons that follow, however, we believe that the Single Convention does not require DEA to place marijuana in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific controls that follow from a drug's placement on a particular schedule. And consistent with this conclusion, we believe DEA may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional controls pursuant to the CSA's regulatory authorities.

A.

To begin, nothing in the Single Convention requires the United States to comply with its international obligations by placing a drug in a statutory "schedule" that specifically authorizes all the necessary restrictions. To the contrary, the Single Convention states that parties will implement the Convention using both "laws and *regulations*." Single Convention art. 18(1)(b) (emphasis added); see also *id.* art. 4 (referring to the use of "legislative and *administrative measures*" to carry out the Single Convention (emphasis added)). The Single Convention thus appears to explicitly contemplate a scenario in which DEA decides to implement the United States' obligations through a combination of scheduling and regulatory actions.

As a result, any limitation on satisfying the United States' Single Convention obligations by supplementing a scheduling decision with regulatory action would have to come from domestic law. Nothing in the CSA, however, states that a drug must be placed into Schedule I or II, or any other particular schedule, to comply with the Single Convention. Nor does the CSA expressly foreclose DEA from satisfying the United States' international obligations with a combination of scheduling and regulatory actions. Rather, section 811(d)(1) directs the Attorney General to "control[]" a drug "under the schedule [the Attorney General] *deems most appropriate*" (emphasis added)—language that signals a broad grant of discretion to the Attorney General (and thus DEA), *see Rex Chainbelt, Inc. v. Volpe*, 486 F.2d 757, 761 (7th Cir. 1973). To be sure, the very same language could be read to mean that DEA must select a schedule without resort to regulatory supplementation. *See* 21 U.S.C. § 802(5) (defining "control" as "to add a drug . . . to a *schedule*" (emphasis added)). But we are reluctant to adopt a restrictive reading of such broad discretionary language, particularly when doing so would preclude DEA from relying on regulatory supplementation to close even relatively minor gaps between a schedule and the United States' international obligations. Indeed, consistent with this reading, DEA has previously placed a drug with the psychoactive chemicals found in cannabis into Schedule V and then imposed additional controls through regulation to comply with the United States' international obligations. *See* 83 Fed. Reg. 48,950, 48,952 (Sept. 28, 2018).[8]

The CSA's varied, and potentially conflicting, purposes further show why it is appropriate to read section 811(d)(1)'s broad grant of authority in this way. Consider a hypothetical case in which the Single Convention imposes obligations that DEA determines would, absent regulatory action,

[8] We have taken a similar interpretive approach to section 811(d)(1)'s language specifying that the Attorney General meet international obligations "without regard" to the findings and procedures otherwise required by sections 811(a) through (b) and 812(b). Rather than viewing this language as precluding the Attorney General from following ordinary scheduling practices when international obligations are involved, both our Office and the D.C. Circuit have understood it to allow the Attorney General to identify which schedules would satisfy the United States' international obligations with respect to a particular drug, and then—if more than one schedule would do so—select which schedule to use through the section 811(a) through (b) and 812(b) procedures. Lawton Memo at 10; *accord NORML II*, 559 F.2d at 747.

require placement on Schedule I or Schedule II, but DEA has also determined that the same drug's abuse potential, medical usefulness, and health effects warrant placing the drug in Schedule III. *See* 21 U.S.C. §§ 801(1), (2), 812(b)(3). In such a circumstance, reading section 811(d)(1) to allow for consideration of regulatory action allows DEA to conclude that Schedule III is the "most appropriate" schedule by pairing that choice with regulatory actions that ensure compliance with the Single Convention. This enables DEA to comply with the United States' international obligations while furthering the CSA's other purposes, thus fulfilling both sets of objectives.

The broad regulatory authority provided by the CSA further suggests that DEA need not rely on scheduling decisions alone to comply with the Single Convention. The CSA authorizes the Attorney General (and thus DEA) both to "promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," *id.* § 821, and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions," *id.* § 871(b). Courts recognize that broad, discretionary language such as this conveys "extensive" regulatory authority, *Volpe*, 486 F.2d at 761; *see also, e.g.*, *Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1209 (D.C. Cir. 2020)—and, here, the language by its plain terms would seem to encompass regulatory actions that DEA may take to satisfy Single Convention obligations not met by a drug's schedule alone.

Likewise, the CSA provides the Attorney General with a number of more specific regulatory authorities that DEA may use to enable compliance with particular Single Convention obligations, such as the CSA's registration requirements. Subject to certain limited exceptions, section 822(a) requires "[e]very person who manufactures or distributes" or "dispenses" a drug to "obtain annually a registration issued by the Attorney General in accordance with rules and regulations promulgated by him," and section 822(b) further specifies that "[p]ersons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances . . . are authorized to possess, manufacture, distribute, or dispense such substances . . . to the extent authorized by their registration." These provisions give DEA the authority to impose a number of controls on a particular drug through registration. Other CSA

provisions provide similar regulatory authority that could enable a drug on a schedule other than Schedule I or Schedule II to comply with the Single Convention. *See, e.g.*, 21 U.S.C. §§ 823(e), (f), 827(e), 952(b)(2), 953(e)(2), 958(c).

Finally, past practice also supports our conclusion. Specifically, in addition to the example recounted above of DEA imposing additional controls through regulation to comply with the United States' international obligations, *see* 83 Fed. Reg. at 48,952, we understand that DEA previously has relied on a combination of the Attorney General's registration power and general regulatory authority to promulgate extensive safety and security regulations that govern manufacturers and distributors of controlled substances. *See* 21 C.F.R. §§ 1301.71–.77. And our Office has previously read the Attorney General's authority to register manufacturers broadly to permit the imposition of certain controls that would enable compliance with the Single Convention. *See Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs*, 42 Op. O.L.C. __, at *24 (June 6, 2018) ("*Licensing Marijuana Cultivation*"). These prior regulatory actions indicate that the broad and varied provisions discussed above provide authority that may be used to impose additional controls to satisfy the United States' international obligations.

We recognize that reading the CSA as allowing DEA to use regulatory authorities to close gaps in our compliance with international obligations could be viewed as in tension with certain aspects of the CSA's text and structure. As the Lawton Memo noted, several provisions of the CSA implementing controls required by the Single Convention draw a distinction between Schedules I and II, on the one hand, and Schedules III through V, on the other, in a manner that can be read to suggest that Congress understood the United States would comply with its Convention obligations by placing drugs into Schedules I or II. Lawton Memo at 12; *see, e.g.*, 21 U.S.C. §§ 823(a), (d), (e), 826(a), 842(b), 952(a), (b), 958(a), (c). Moreover, Congress designed the CSA to include five schedules, each with a distinct bundle of requirements and consequences, and allowing DEA to add or subtract controls would arguably have the practical effect of enabling DEA to create new schedules.

These arguments have some force, but they do not carry the day. Since the CSA's enactment, Congress has amended the Act in a manner that indicates the distinction between Schedules I and II and Schedules III

through V may not be as sharp as the argument above suggests. *See infra* Part IV.B (describing how amendments that added sections 952(b)(2), 953(e)(2), and 827(e) enable the United States to meet certain Single Convention obligations while placing nonnarcotic drugs in Schedule III). In any event, right alongside the provisions that could *impliedly* suggest Schedules I and II will be used to comply with the United States' Single Convention obligations are provisions that *expressly* grant the Attorney General (and thus DEA) both broad discretion to select the schedule "most appropriate" to satisfy the United States' international obligations, *see* 21 U.S.C. § 811(d)(1), and broad regulatory authority, *see, e.g.*, *id.* §§ 821, 871(b). And given the plain meaning of the CSA's regulatory provisions, we do not believe that the CSA's five-schedule structure can be reasonably understood to preclude DEA from taking at least some regulatory actions to comply with the United States' international obligations. Indeed, it would be particularly strange to view DEA as so constrained in the context of treaty compliance, given section 811(d)(1)'s express grant of broad discretion to meet international obligations. We therefore believe that something more than such textual and structural inferences are needed to foreclose use of these broad and express statutory grants of regulatory authority to impose additional controls to meet the United States' international obligations.

Thus, while we take no position on the full extent to which DEA may use the CSA's broad regulatory authority to impose additional controls to meet international obligations, we do not read the CSA as precluding DEA from ever satisfying the United States' Single Convention obligations by supplementing scheduling decisions with regulatory action. Rather, we believe that the CSA provides DEA with the discretion to decide, at least in some circumstances, that such a scheduling and regulatory approach is the most appropriate way to strike a balance between the CSA's varied—and potentially conflicting—purposes of curtailing the improper use of drugs with abuse potential, complying with the United States' international obligations, and ensuring that medically useful drugs remain available for legitimate purposes. *See* 21 U.S.C. § 801(1), (2), (7).

B.

We next consider the specific question of whether DEA may comply with the United States' obligations under the Single Convention by supplementing a decision to place marijuana in Schedule III with regulatory action.

As a threshold matter, we understand that, if marijuana were placed on Schedule III, the gap that DEA would need to fill would be modest. To be sure, the Lawton Memo and the D.C. Circuit expressed concern that placing marijuana into Schedule III would create compliance concerns with respect to certain Single Convention requirements. In its submission to us, however, the State Department observed that, even if marijuana were listed in Schedule III, most of the United States' Single Convention obligations would continue to be met. *See* State Response at 4–7. The State Department's view reflects amendments to the CSA that postdate the Lawton Memo (from 1972) and the D.C. Circuit's consideration of the issue (in 1977) and that specifically authorize certain controls required by the Single Convention to be placed on drugs outside Schedules I and II. Given these amendments, many of the gaps previously identified in Single Convention compliance would no longer exist if marijuana were placed in Schedule III.

In particular, the Lawton Memo and D.C. Circuit both pointed to the manufacturing and import quotas required by Article 21 of the Single Convention as potential gaps, *see* Lawton Memo at 12–13, while the D.C. Circuit also identified the estimates and statistical reports required by Articles 19 and 20 and the import and export authorizations required by Article 31(4), *see NORML II*, 559 F.2d at 751 n.71. In 1978, however, Congress enacted 21 U.S.C. § 827(e), which specifically authorizes the Attorney General, among other things, to prescribe measures necessary to comply with the reporting requirements of Articles 19 and 20 of the Single Convention for drugs in any schedule, not just those in Schedules I and II. *See* Psychotropic Substances Act of 1978, Pub. L. No. 95-633, § 104, 92 Stat. 3768, 3772. In addition, in 1984 Congress amended the CSA provisions that implement the import and export permit requirements to specifically authorize the use of permits for a nonnarcotic Schedule III drug. *See* 21 U.S.C. §§ 952(b)(2), 953(e) (enacted by the Controlled Substances Penalties Amendments Act of 1984, Pub. L. No. 98-473,

§§ 521–522, 98 Stat. 1837, 2075–76). If marijuana, a nonnarcotic drug, were placed in Schedule III, we believe these statutory provisions would ensure compliance with both the import quota obligation of Article 21 and the import and export authorization requirements of Article 31(4).

These subsequent enactments address most of the concerns the Lawton Memo and D.C. Circuit identified, with the exception of the manufacturing quota requirements of Article 21 of the Convention. But we believe this remaining gap is addressable using the CSA's regulatory authorities. Several different authorities appear potentially applicable. A regulation imposing a manufacturing quota on a drug would fall easily within the broad language of section 821, as it would be "relat[ed] to the . . . control of the manufacture" of a drug. 21 U.S.C. § 821. DEA likewise could deem a regulation imposing a manufacturing quota as "necessary and appropriate for the efficient execution of" the CSA function of controlling drugs to meet the United States' international obligations. *Id*. § 871(b); *see id.* § 811(d)(1). By their plain terms, the CSA's registration authorities would also give DEA the authority to impose a manufacturing quota on a particular drug through regulation: no person can manufacture a drug (including marijuana) without a registration issued by DEA, *see id.* § 822(a), and in that registration DEA can limit the "extent" to which any person is "authorized to . . . manufacture" marijuana under their registration, *id*. § 822(b). Section 823(e) provides yet another potential source of authority for imposing a manufacturing quota on a Schedule III drug, as DEA could conclude under section 823(e) that registrations to manufacture marijuana would be "inconsistent with the public interest" unless a quota consistent with Article 21 of the Single Convention was implemented to maintain "effective controls against diversion." *Id.* § 823(e); *see also Oregon*, 546 U.S. at 260 (identifying similar language in section 823(a) as providing regulatory authority).[9]

[9] We note that section 823(a) provides that the Attorney General shall register manufacturers of Schedule I and Schedule II drugs upon determining that "such registration is consistent with the public interest and *with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971*." (Emphasis added.) In *Licensing Marijuana Cultivation*, we emphasized section 823(a)'s invocation of international obligations in concluding that DEA could promulgate regulatory controls necessary to meet certain of the United States' obligations under the Single Convention. *See* 42 Op. O.L.C. __, at *24. Although section 823(e) does not include a similar requirement to

In concluding that the CSA provides numerous sources of authority that could be used to impose a manufacturing quota, we recognize that section 826 expressly requires manufacturing quotas for drugs in Schedules I and II.[10] But that requirement should not be read as implicitly foreclosing the imposition of such quotas for drugs in Schedules III through V. As the D.C. Circuit has recognized, "a congressional mandate in one section and silence in another often suggests not a prohibition but simply a decision . . . to leave the question to agency discretion." *Catawba County v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (per curiam) (quotation marks omitted).

We therefore conclude that both the Single Convention and the CSA permit DEA to place marijuana in Schedule III while imposing additional controls, pursuant to the CSA's regulatory authorities, to close a modest gap between the requirements of the Single Convention and the requirements that follow from placement on Schedule III.

V.

For the reasons set forth above, we conclude, first, that DEA's current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS's two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by

consider international obligations, it does require the Attorney General to consider whether registration is "inconsistent with the public interest," 21 U.S.C. § 823(e), and complying with the United States' international obligations is plainly in the public interest. Against this backdrop, we do not read Congress's silence with respect to international obligations in section 823(e) as precluding DEA from relying on that section to comply with international obligations. *See Catawba County v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (per curiam).

[10] Although the CSA refers to quotas on the "production" of drugs and the Single Convention to quotas on the "manufacture" of drugs, we understand the scope of these terms to largely overlap. The CSA defines "production" to include the "manufacture, planting, cultivation, growing, or harvesting of a controlled substance," 21 U.S.C. § 802(22), and, in turn, defines "manufacture" to include the "production, preparation, propagation, compounding, or processing of a drug," *id.* § 802(15). The Single Convention defines "manufacture" to mean "all processes . . . by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs," Single Convention art. 1(1)(n), but excludes "the separation of . . . cannabis and cannabis resin from the plants from which they are obtained," *id.* art. 1(1)(t).

FDA and would not satisfy DEA's five-part test. Second, we conclude that HHS's overall CAMU recommendation is not binding on DEA and that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process. Finally, we conclude that neither the Single Convention nor the CSA requires marijuana to be placed into Schedule I or II. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific restrictions that follow from a drug's placement on a particular schedule. As a result, DEA may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the CSA's regulatory authorities.

CHRISTOPHER C. FONZONE
Assistant Attorney General
Office of Legal Counsel

NPRM

From: Grant, Igor <igrant@health.ucsd.edu>
Sent: Thursday, September 26, 2024 5:44 PM
To: NPRM
Cc: cmcr@ucsd.edu
Subject: [EXTERNAL] Docket No. DEA-1362

Dear Mr. Strait,

In response to your letter of 9/10/24, I am the Director of UC San Diego's Center for Medicinal Cannabis Research (CMCR), which has been charged by the State of California to develop evidence on the potential usefulness and health risks of cannabis and its constituents. The CMCR has been conducting and supporting clinical and pre-clinical cannabis research for almost 25 years, examining the potential health benefits across a range of medical and psychiatric conditions, and public safety risks, associated with THC, CBD and minor cannabinoids across different methods of administration (e.g., smoking, vaporizing, oral). Our group has published peer-reviewed research in high-tier journals, and received funding from NIH, the State of California, and philanthropy.

To further clarify how I meet the classification of an “interested person” who may be “adversely affected or aggrieved” by the proposed rule, there is no question that having cannabis in Schedule I has posed serious barriers to our examination on the effects of cannabis on public health.

Whereas a rescheduling of cannabis into Schedule III would make some aspects of medical research easier, e.g., related to strict chain of custody, etc., the rescheduling proposal still leaves in place many uncertainties regarding its effect on facilitating research regarding the critically important public health issue of cannabis use.

For example, rescheduling, as currently proposed, may not address challenges in expanding the availability of products that researchers need in order to study the types of products and administration methods that are increasingly being used by the public, particularly where medicinal cannabis is permitted. Since this affects about 50% of the US population, we consider this a matter that is important to discuss. As another example, the definitions of hemp (and derived cannabinoids) and marijuana, including their scheduling status, needs significantly greater clarity.

During my presentation I will discuss the above issues and provide real-world examples of how such limitations impact our ability to conduct cannabis research.

Thank you for providing me with this opportunity.

Igor Grant MD
Mary Gilman Marston Distinguished Professor
Department of Psychiatry
Director
HIV Neurobehavioral Research Program and Center for Medicinal Cannabis Research
UCSD
220 Dickinson St # B,

San Diego, CA 92103
VOICE: 1-619-543-4733
igrant@health.ucsd.edu

Outlook

[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Ariana Fleishman <ariana.fleishman@gmail.com>
Date Fri 9/27/2024 8:09 AM
To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

While I acknowledge the proposed rescheduling, I firmly believe that marijuana should be descheduled entirely. My interest in this proceeding stems from the following points:

1. The medical benefits of marijuana and its potential to improve the quality of life for many patients, especially those who are incarcerated and suffer from health issues exacerbated by their imprisonment. Rescheduling could inadvertently reinforce the stigmatization of marijuana as a political tool rather than recognizing its therapeutic properties.
2. The importance of acknowledging the long-standing impact of marijuana prohibition on marginalized communities, leading to mass incarceration and injustice. Descheduling marijuana would be a crucial step toward rectifying these historical wrongs and alleviating the burden on those who are currently imprisoned for marijuana-related offenses.
3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.

I appreciate the opportunity to participate in this important discussion.

Sincerely,
Ariana
Sent from my iPhone

From: Mrs.CYNTHIA MATEO <cynthiamateo2241@gmail.com>
Sent: Friday, September 27, 2024 3:13 PM
To: NPRM
Subject: [EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

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I appreciate the opportunity to participate in this important discussion.

Sincerely, Cynthia mateo

Sent from my iPhone

September 27, 2024
Etienne Fontan
Council Member
Veterans Action Council
1700 Shattuck Ave Apt 207
Berkeley, CA 94709
510.812.8386

To Whom It Will Concern,

510-812-8386 - FROM THE DESK OF Etienne Fontan-
EMAIL: atn420@gmail.com
————-
27 Sept 2024, I hereby give notice that I wish to present and argue my position during the upcoming Hearing by an Administrative Law Judge on cannabis rescheduling:

RE: Schedules of Controlled Substances: Rescheduling of Marijuana — Hearing on the Proposed Rule by the Drug Enforcement Administration

https://www.federalregister.gov/documents/2024/05/21/2024-11137/schedules-of-controlled-substances-rescheduling-of-marijuana

I am a disabled United States Army Combat Veteran, and the proposed rule will harm me.

Etienne Fontan — Written Notice as interested party:
I have suffered injury from schedule #1 placement of cannabis, and while schedule #3 rescheduling will resolve some of these issues; I will still continue to suffer unnecessary harm and continued injury under the proposed schedule #3.

Schedule #3 is unacceptable, given the totality of the evidence and experience we have from the many states 'l cannabis and adult recreational cannabis access programs, as well as academic and scientific record.

State medicinal access programs and adult recreational access programs operate in a consensus fashion under state laws that more closely align with schedule #5 than schedule #3.

The Department of Veterans Affairs - Hospital System, given the fact that schedule #3 will require time consuming FDA approval before such medicines will be able to be dispensed from VA pharmacies will not be able to integrate cannabis into Veterans' pain management or Post Traumatic Stress treatment as they certainly would be able to under a schedule #5 placement or by de-scheduling.

Veterans Affairs hospitals, under schedule #3, will not be able to facilitate cannabis prescriptions until FDA approves new cannabis medicines. Such FDA approvals will be granted for products based upon the many preparations available in dispensaries operated under state laws. This process

is onerous, and it takes many years for FDA approval for a similar product that is already widely available from said dispensaries.

Schedule #5 placement will allow my VA doctor to prescribe/recommend my cannabis medication and for the Veterans Affairs Administration to pay for the product that I would then purchase myself in much the same way that Veterans currently receive a clothing allowance and then buy their own
clothes.

I suffer from Gulf War Illness/Syndrome (GWI/S) along with multiple injuries I sustained during my military service, and I have received care from VA hospitals. I was previously prescribed Marinol [FDA-approved THC], and it caused side effects of anxiety that were too much to continue using. I have used whole cannabis preparations from dispensaries in California, stemming from a doctor's recommendation.

These cannabis products improved the quality of my life repeatedly by helping me manage better my pain and other symptoms of GWI/S. Current VA policy spells out how a doctor's VA, because of schedule #1 placement of cannabis, cannot write a 'recommendation' for cannabis. This VA policy has made it necessary for me, a 100% total and permanently rated disabled Veteran, to have to leave the VA and create a new doctor relationship outside the VA hospital system at my own expense. Suppose cannabis is placed in schedule #3. In that case, my situation will be only partially repaired as I will then be able to, for the first time, have a VA doctor write my 'recommendation' for cannabis but will still have to pay for my medication out of pocket even though all of my other medications stemming from my service-connected injuries are covered by the VA.

Schedule #5 is more appropriate - follow the experience, not just the evidence and law, Given the experience in the 30+ states and territories enacting such laws since 1996 and the fact that medical boards, state legislatures, hospital systems, nurses associations, patients, their families, and their Communities have carefully thought through the many access issues and have converged on a consensus policy supporting over-the-counter access, which the DEA should instead reschedule to schedule #5 to reflect this reality.

It should be noted that connected to the 30,000 medical care providers and the 6,000,000 patients acknowledged by the FDA, accessing cannabis through a state-authorized medical cannabis recommendation is a mountain of real-world experience. The FDA makes a conservative opinion based on evidence, but the experience is what the FDA lacks; the DEA should recommend based on experience, law, and evidence.

I ask the court to rule that the DEA reschedule cannabis to Schedule #5 or deschedule outright, reflecting its medicinal potential, the overwhelming evidence of its benefits as well as the experience of the millions of patients and their communities. This experience includes state panels dedicated to hearings on various cannabis subject matters.

The conclusion of these many million human hours in the many states has resulted in what
we experience today: a consensus around handling cannabis as an over-the-counter medication. I have participated in some of these state processes and can attest to the professionalism of the

membership and the seriousness under which they carried out their tasks. These are well-thought-through, experience-based recommendations that stand toe-to-toe with any evidence-based evaluation of the FDA.

Background documents & Links:
‘Cannab's’ ontol'gies: Conceptual issues with Cannabis and cannabinoids terminology :
https://journals.sagepub.com/doi/10.1177/2050324520945797
Cannabis amnesia – Indian hemp parley at the Office International d’Hygiène Publique in 1935: https://www.researchgate.net/publication/360540702_Cannabis_amnesia_-_Indian_hemp_parley_at_the_Office_International_d'Hygiene_Publique_in_1935

Veterans Action Council Green Paper:
https://www.veteransactioncouncil.com/the-green-paper-1

Outlook

[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Ian Patrick Patriarca <irpmarketing0805@gmail.com>
Date Fri 9/27/2024 7:43 AM
To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

While I acknowledge the proposed rescheduling, I firmly believe that marijuana should be descheduled entirely. My interest in this proceeding stems from the following points:

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2. The importance of acknowledging the long-standing impact of marijuana prohibition on marginalized communities, leading to mass incarceration and injustice. Descheduling marijuana would be a crucial step toward rectifying these historical wrongs and alleviating the burden on those who are currently imprisoned for marijuana-related offenses.
3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.

I appreciate the opportunity to participate in this important discussion.

Sincerely,
Ian Patrick Patriarca

Outlook

[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Jessica Garza <jes.garza20@gmail.com>
Date Fri 9/27/2024 7:28 AM
To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

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3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.

I appreciate the opportunity to participate in this important discussion.

Sincerely,

Jessica Garza

Outlook

[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Jonathan Frank <jonathanfrank84@icloud.com>
Date Fri 9/27/2024 2:15 PM
To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

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I appreciate the opportunity to participate in this important discussion.

Sincerely,
Jonathan Frank

Sent from my iPhone

Outlook

[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Rafael Acevedo <bookingruleyalabel@gmail.com>
Date Fri 9/27/2024 12:20 PM
To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

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While I acknowledge the proposed rescheduling, I firmly believe that marijuana should be descheduled entirely. My interest in this proceeding stems from the following points:

1. The medical benefits of marijuana and its potential to improve the quality of life for many patients, especially those who are incarcerated and suffer from health issues exacerbated by their imprisonment. Rescheduling could inadvertently reinforce the stigmatization of marijuana as a political tool rather than recognizing its therapeutic properties.
2. The importance of acknowledging the long-standing impact of marijuana prohibition on marginalized communities, leading to mass incarceration and injustice. Descheduling marijuana would be a crucial step toward rectifying these historical wrongs and alleviating the burden on those who are currently imprisoned for marijuana-related offenses.
3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.

I appreciate the opportunity to participate in this important discussion.

Sincerely, Rafael Acevedo

TCP

September 27, 2024

Hon. Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: Notice of Desired Participation in Drug Enforcement Administration Hearing with Respect to the Proposed Rescheduling of Marijuana; Docket No. DEA-1362 (August 28, 2024)

Dear Administrator Milgram:

The Commonwealth Project presents these comments to the Drug Enforcement Administration ("DEA") in response to its August 28 Notice of Hearing on Proposed Rulemaking regarding the reclassification of marijuana from Schedule I to Schedule III of the Controlled Substances Act. First and foremost, The Commonwealth Project applauds the historic action taken by the Department of Justice ("DOJ") and the DEA to initiate rescheduling of marijuana from Schedule I to Schedule III under the Controlled Substances Act ("CSA").

The Commonwealth Project is a humanitarian effort working to legitimize and integrate medical cannabis within the existing US health care system. Specifically, it's the goal of the Commonwealth Project to improve the health experience of individuals 65+ by allowing medical cannabis to be part of their overall health care. The Commonwealth Project is laying the groundwork for a robust and patient-centric research and care demonstration model for medicinal cannabis that takes into consideration the unique healthcare delivery challenges faced by America's seniors.

In its July 22 comments submitted to the DEA in response to its Notice of Proposed Rulemaking and Request for Comments regarding the reclassification of marijuana from Schedule I to Schedule III of the Controlled Substances Act, the Commonwealth Project encouraged the DEA and the White House to move as expeditiously as possible on rescheduling. If a final rule is not published before the end of the year, the scientific community will remain limited in its capacity to move forward with research and demonstration trials that will bring the much needed and undisputed benefits of these therapies to as many seniors as possible.

Federal lawmakers in opposition to the DEA's proposed rescheduling of cannabis from Schedule I to Schedule III have formally written to agency officials expressing their view that the rule "fails to provide adequate science and data to support moving marijuana to schedule III and should not have been signed or published."[1] While recent changes to federal law under the Medical Marijuana and Cannabidiol Research Expansion Act (MMCREA) aim to expand

[1] https://mjbizdaily.com/wp-content/uploads/2024/07/Lawmaker-rescheduling-letter.pdf

research of medical marijuana, there remains a deficiency in available research on the long-term health impacts of marijuana use or potential medical use.

However, further delaying the rescheduling of cannabis will only further exacerbate the challenges that potential participants in scientific studies and pilot programs currently face, including uncertainty about whether there will be repercussions if they take part in such research activities. There is an entire industry waiting to address the health needs of traditionally underserved portions of the 65+ population by providing critical research that could increase access to life-altering medical therapies.

By swiftly rescheduling cannabis from Schedule I to Schedule III, there will be greater, but not complete, certainty for seniors, researchers, and physicians to engage in research or pilot healthcare projects that examine the benefits and distribution of medical cannabis. Therefore, the Commonwealth Project holds that the final rule mandating rescheduling should include, at a minimum, an explicit assurance that participants, researchers, and individuals and/or organizations that engage or participate in health care projects will suffer no adverse consequences from any Federal agency.

Vicente.

1553 Platte Street, Suite 310
Denver, CO 08202
Tel: 303-860-4501

California · Colorado · Florida · Massachusetts · Michigan · Minnesota · New Jersey · New York · Texas

September 27, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

Subject: Notice of Appearance

Dear Administrator Milgram:

Please take notice that Vicente LLP respectfully requests the opportunity to appear in the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the "Proposed Rule"), Docket No. DEA-1362, currently scheduled for December 2, 2024, at 9:00am E.T., per 89 Fed. Reg 70,148.

(A) Vicente LLP has standing to participate in the hearing. 21 C.F.R. § 1300.01(b) allows that "any person adversely affected or aggrieved by any rule or proposed rule issuable" under 21 U.S.C. 811 has standing to appear at the hearing for the Proposed Rule ("Interested Person").[1] Vicente LLP is an Interested Person and falls within the Controlled Substances Act's ("CSA") zone of interests. Further, Vicente LLP will be directly and adversely affected and aggrieved by the Proposed Rule, if finalized. Vicente LLP's status as an Interested Person is further detailed in the enclosed submission.

(B) Among other things, Vicente LLP desires to be heard, has unique expertise, and would provide invaluable insights into: (i) the appropriate schedule for marijuana;[2] (ii) the U.S.' ability to reschedule (or de-schedule) marijuana while remaining compliant with its international treaty obligations;[3] (iii) the practical consequences of rescheduling marijuana under the relevant statutory and regulatory frameworks;[4] and (iv) state medical marijuana programs, particularly as they relate to the harms that program participants (i.e. patients and medical professionals) face with marijuana in Schedule I. Further details about the objections or issues on which Vicente LLP desires to be heard are provided in the enclosed submission.

(C) As the only national law firm dedicated exclusively to servicing participants in the 38 state-regulated marijuana regulatory systems, Vicente LLP is uniquely situated to assist the Drug Enforcement Agency's ("DEA") administrative decision making. Since its 2010

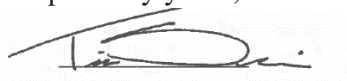
[1] Pursuant to 21 C.F.R. § 1300.01(b), "person" includes "any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity."
[2] "DEA believes that additional information arising from this rulemaking will further inform the findings regarding the appropriate schedule for marijuana." 89 Fed. Reg. 44,601 (May 21, 2024).
[3] "In proposing an appropriate schedule for marijuana, the Attorney General must also consider compliance with the treaty obligations of the United States." 89 Fed. Reg. 44,620 (May 21, 2024).
[4] "DOJ is seeking comment on the practical consequences of rescheduling marijuana into schedule III under the relevant statutory frameworks." 89 Fed. Reg. 44,621 (May 21, 2024).

founding in Colorado, Vicente LLP has, among other things, (i) represented and advocated for thousands of medical marijuana patients, doctors, researchers, businesses, and other stakeholders as they navigate the states' rapidly evolving regulatory regimes; (ii) played major roles in drafting relevant laws and amendments thereto; (iii) opined, wrote and spoke on a host of legal issues relevant to the Proposed Rule; and (iv) participated in groundbreaking litigation arising from the state-legalization of marijuana. Over the past 14 years, Vicente LLP, its attorneys and professionals not only have had a front-row seat to the unique challenges faced by its clients; they too have experienced first-hand the limitations to their engagement of essential services, including banking, healthcare, insurance, marketing[5] and financing caused by marijuana's status as a scheduled narcotic. Vicente LLP, its members, and its clients would be significantly impacted by the Proposed Rule, if finalized. Vicente LLP's positions with regard to the particular objections or issues are further detailed in the enclosed submission.

All notices to be sent pursuant to this appearance should be addressed to:

Timothy D. Swain
Vicente LLP
800 Boylston Street, 26th Floor
Boston, MA 02199
T.Swain@VicenteLLP.com

Respectfully yours,



Timothy D. Swain

[5] *Cannabis Biz Could Advertise Under Schedule III, Congressional Report Says*, Marijuana Moment (July 30, 2024), https://www.marijuanamoment.net/cannabis-biz-could-advertise-under-schedule-iii-congressional-report-says-newsletter-july-30-2024/.

Vicente.

September 27, 2024

Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, Virginia 22152

Drug Enforcement Administration
Attn: DEA Federal Register
Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Request to Participate in a Hearing & Notice of Appearance
Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597, Docket No. DEA-1362

Administrator Milgram:

Pursuant to 21 C.F.R. § 1308.44(c) and § 1316.48, Vicente LLP submits, as an Interested Person, this Request to Participate in a Hearing and Notice of Appearance ("Request"). Vicente LLP has attached declarations as enclosures to this Request, stating the relevant expertise of our proposed experts and fact witnesses for the December 2, 2024, hearing being held pursuant to 89 Fed. Reg. 70,148 ("Notice of Hearing"). If selected to testify at the hearing, Vicente LLP will submit detailed written testimony, to accompany our in-person testimony, to DEA's Administrative Law Judge ("ALJ").

Vicente LLP represents, among other clients, businesses, organizations and individuals participating in or serving the state-legal marijuana and hemp industries. As established herein, Vicente LLP qualifies as an Interested Person within the relevant "zone of interests" and will be adversely affected or aggrieved by this proposed rule, entitled Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (May 21, 2024) (the "Proposed Rule"), if finalized.

As an Interested Person, Vicente LLP has standing to participate in the hearing. Additionally, among other things, Vicente LLP has unique expertise and can provide invaluable insights into: (i) the appropriate schedule for marijuana;[6] (ii) the U.S.' ability to reschedule (or de-schedule) marijuana while remaining compliant with its international treaty obligations;[7] (iii) the practical consequences of rescheduling marijuana under the relevant statutory and regulatory frameworks;[8] and (iv) state medical marijuana programs, particularly as they relate to the harms that program participants (i.e. patients and medical professionals) face with marijuana in schedule I. Vicente LLP is prepared to present expert testimony on these issues that would materially assist a DEA ALJ in preparing a sound and well-supported administrative decision.

[6] *See Supra*, Note 2.
[7] *See Supra*, Note 3.
[8] *See Supra*, Note 4

A. Background

On May 21, 2024, DOJ issued a Notice of Proposed Rulemaking, Schedules of Controlled Substances: Rescheduling of Marijuana. Proposed Rule at 44,597. The Proposed Rule noted that DEA may hold a hearing to "receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III on the list of controlled substances." *Id.* at 44,599 (cleaned up). Concurrently, the agency is considering "marijuana-specific controls that would be necessary to comply with relevant treaty obligations in the event that, after the hearing, a final order reschedules marijuana." *Id.* DEA will presumably consider any such updated controls during this rulemaking, and Vicente LLP is prepared to submit testimony on this matter.

This request to participate in a hearing is timely filed. As noted in the Notice of Hearing, Interested Persons must submit notices of appearance with a postmark, or receipt deadline if emailed, of September 30, 2024.

This Request serves to inform DEA that Vicente LLP is an Interested Person and respectfully requests the ability to fully participate in DEA's rulemaking process, including at the December 2, 2024, hearing.

B. Who is Vicente LLP?

Vicente LLP is a prominent national law firm that has been intimately involved in the passage and promulgation of state legal and regulatory frameworks governing the marijuana and hemp industries throughout the United States. Vicente LLP's predecessor company was Vicente Consulting, which advised medical marijuana patients and caregivers. For the past 14 years, Vicente LLP has represented individuals, businesses, organizations, patients, caregivers, and doctors participating in the marijuana and hemp industries; counseled their compliance with 38 state-specific legal regimes; and advocated for and protected its clients' interests. Founded in 2010 in response to the evolving legal landscape of marijuana and hemp, Vicente LLP works to influence public policy, promote industry growth, and enhance the state and international programs that ensure safe, regulated access to medical and adult-use cannabis. Headquartered in Denver, CO, with offices in ten states and servicing clients in every state with a state-legal marijuana program, Vicente LLP collaborates closely with state, federal, and international policymakers, regulatory agencies, researchers, standards organizations, accreditation bodies, and industry stakeholders to foster viable, safe, regulated, and compliant marijuana and hemp programs.

Vicente LLP is particularly focused on areas such as patient access to medicine, public health, consumer protection, product safety, industry standards, legislative advocacy, education, research, and international treaty compliance within the marijuana and hemp sectors. The firm provides its clients with critical information on regulatory changes, market trends, and legal challenges. Vicente LLP has a vested interest in seeing that its business clients succeed and that they are economically viable, and in ensuring that Americans have access to safe, regulated, medicinally beneficial marijuana and hemp products.

Vicente LLP has spent extensive time, money, and other resources to advocate for a regulated, responsible marijuana marketplace. The firm's interests would be at risk if Vicente LLP were not permitted to participate in the formal rulemaking process to the fullest extent permitted by law.

The Proposed Rule directly affects Vicente LLP. Specifically, if the Proposed Rule is adopted, Vicente LLP will be adversely affected by the impact on (i) the firm's ability to market its services to potential new clients; (ii) the firm's access to adequate banking resources; (iii) the firm's access to adequate healthcare options for its employees; (iv) the firm's access to adequate insurance, including malpractice insurance; and (v) the firm's ability to secure adequate financing, including, but not limited to, programs similar to the Paycheck Protection Program—which Vicente LLP could not access due to the ancillary marijuana-related work it does.

If the DEA eschews the Proposed Rule and decides that marijuana should remain on schedules I or II, that decision would also adversely affect Vicente LLP's clients with significant tax consequences. These tax consequences would then adversely affect Vicente LLP because its clients would be less able to pay their current balances to Vicente LLP for services rendered, and they would also be less able to pay for Vicente LLP's services moving forward. This would not be the case if marijuana were classified outside of schedules I or II.

C. Objections or Issues Concerning Which Vicente LLP Desires to be Heard

The Proposed Rule represents a seismic shift in how the federal government proposes to regulate the nation's marijuana market.

Placing Marijuana outside of schedule I better aligns the U.S. with its international treaty obligations. However, leaving marijuana in schedule I, or simply moving it to a lower schedule, is harmful to the U.S.' ability to protect against more harmful substances. The resources spent on enforcing marijuana prohibition are better spent addressing the opioid crisis and other prominent public health risks. Additionally, the primary focus of the drug treaties is to ensure medical access to drugs. The current scheduling of marijuana disregards this obligation. Placing marijuana outside of Schedule I would better align the U.S. with its drug treaty obligations.

While the Proposed Rule would reschedule marijuana to schedule III, certain crucial consequences of this momentous decision remain unanswered. Vicente LLP is well positioned to present evidence addressing these unanswered questions. Vicente LLP is a law firm with clients that include many of the leading participants in the state-legal, regulated marijuana programs. Some of Vicente LLP's clients are "plant touching" companies, some provide ancillary services to the state-legal industry, and some are non-profit research and advocacy organizations. With marijuana moved outside of schedule I, DEA will need to amend its regulations to account for U.S. drug treaty obligations. Such regulatory changes could negatively affect state-legal marijuana operators, if not addressed appropriately. As such, Vicente LLP is prepared to testify on what regulations DEA will need to update to ensure drug treaty compliance.

D. Vicente LLP Meets the Requirements for Standing

Vicente LLP has standing to participate in a hearing if one occurs. Vicente LLP is an Interested Person and falls within the CSA's zone of interests. Further, Vicente LLP will be both directly and indirectly adversely affected or aggrieved by the Proposed Rule, if finalized.

1.

The Proposed Rule is a "scheduling action" issued under 21 U.S.C. § 811(a). Id. at 44,598; id. at 44,621. The Administrative Procedure Act ("APA"), the CSA, and DEA regulations set out the governing standards for this scheduling action and related rulemaking proceedings. *See* id. at 44,598–99.
Under the APA, 5 U.S.C. § 555(b), "an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding," "[s]o far as the orderly conduct of public business permits." DEA regulations accordingly provide that an Interested Person may file a request to participate in a hearing. 21 C.F.R. § 1308.44(c).

As the Proposed Rule was promulgated under 21 U.S.C. § 811(a), DEA's definition of Interested Person may apply here. *See* Proposed Rule at 44,598; id. at 44,621. We note that DEA has not formally defined "adversely affected or aggrieved" for purposes of the definition of an Interested Person." *See* In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT, DEA Dkt. No. 22-15 (May 6, 2022) at 2 ("ALJ Order"). ALJs have correctly concluded that it is sufficient that a person falls within the CSA's "zone of interests" to be considered adversely affected or aggrieved. *See* id. at 5–6. As the discussion that follows demonstrates, Vicente LLP qualifies as an Interested Person under this standard; it also qualifies under the narrower article III standard.

2.

Vicente LLP is an Interested Person for two primary reasons.

First, Vicente LLP falls within the CSA's "zone of interests." In May 2022, a DEA ALJ concluded that the test for "adversely affected or aggrieved"—and consequently, Interested Person—was satisfied when the person fell within the "zone of interests" to be regulated by the CSA. ALJ Order at 10. The Supreme Court of the United States has explained that the "zone of interests" test is "not meant to be especially demanding" given Congress' intent to "make agency action presumptively reviewable." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak,* 567 U.S. 209, 225 (2012) (citation omitted).

A party falls "within the zone of interests," the ALJ explained, "if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question." ALJ Order at 5 (quoting *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998)). With regard to the CSA, the Supreme Court has noted that the statute was enacted with "the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2005).

Vicente LLP falls within the CSA's zone of interest. To start, Vicente LLP relies financially on its clients who are regulated by the Proposed Rule and the CSA. Vicente LLP's clients are actively involved in the state-legal marijuana industry, and Vicente LLP is ancillary involved in the same.

Each day, Vicente LLP works to support, and ensure compliance within, the state-regulated market for marijuana and marijuana products and actively fight against the perils of the illicit marketplace.

Additionally, Vicente LLP has spent extensive time, money, and other resources to advocate for a regulated, responsible marijuana marketplace. Vicente LLP's interests and resource expenditures would be at risk if Vicente LLP were not permitted to participate in the formal rulemaking process to the fullest extent permitted by law.

The Proposed Rule also directly affects Vicente LLP. Specifically, if the Proposed Rule is adopted, Vicente LLP will be adversely affected by the impact on (i) the firm's ability to market its services to potential new clients; (ii) the firms access to adequate banking resources; (iii) the firm's access to adequate healthcare options for its employees; (iv) the firm's access to adequate insurance, including malpractice insurance; and (v) the firm's ability to secure adequate financing.

If DEA eschews the Proposed Rule and decides that marijuana should remain on schedules I or II, that decision would also adversely affect Vicente LLP's clients with significant tax consequences. These tax consequences would then adversely affect Vicente LLP because the clients would be less able to pay (as compared to if marijuana were outside of schedules I and II) their current balances to Vicente LLP for services rendered, and they would be less able to pay for Vicente LLP's services moving forward. This directly affects Vicente LLP's ability to generate revenue.

Second, Vicente LLP and its clients would be adversely affected or aggrieved by the Proposed Rule, if finalized. Vicente LLP is prepared to present evidence on these facts at the hearing:

- **The appropriate schedule for marijuana is outside of schedule I and II.**
- **The U.S. is able to comply with its international treaty obligations while placing marijuana outside of schedule I.**
- **There are practical consequences for rescheduling marijuana under the relevant statutory frameworks.**
- **Marijuana has a currently accepted medical use in treatment in the U.S.**
- **State medical marijuana programs evidence a relatively low potential for abuse of marijuana.**
- **Marijuana's schedule I classification has directly harmed patients, doctors, and other stakeholders.**

Third, in addition to the various experts at Vicente LLP who are qualified to present testimony on these facts, two such experts would be simultaneously adversely affected and aggrieved by the Proposed Rule, if finalized. Declarations for both of the experts below are included with this submission.

- Jason Adelstone is Senior Associate at Vicente LLP, where he co-leads the firm's Federal and International Practice Group. He is a leading authority on international cannabis policy and U.S. obligations under the three international drug treaties. Mr. Adelstone has provided guidance to U.S. and foreign government agencies on Treaty compliance and engaged with the INCB on its proposed marijuana recommendations. His knowledge of the U.S.' obligations under the three international drug treaties, the CSA, and DEA regulations that must be accounted for if marijuana is moved out of schedule I will be particularly helpful to the ALJ in acquiring a robust record of the hearing. Additionally, Mr. Adelstone would be, independently, adversely affected and aggrieved by the Proposed Rule, if finalized, because, as an employee of Vicente LLP, he does not have the benefit of the open healthcare market. Because of this, he must pay for dependent healthcare out of his own pocket. If the firm could shop for healthcare plans on the open market, there would be more competitively priced plans, which would allow Vicente LLP to cover dependent healthcare. This is a result of the limited affordable options for healthcare that ancillary marijuana businesses have due to marijuana's classification as a schedule I substance. Mr. Adelstone wishes to participate at the December 2, 2024, hearing in person; he is also willing to provide written testimony if his in-person participation at the hearing is not granted by DEA.

- Shawn Hauser is an equity partner at Vicente LLP, where she co-chairs the firm's Hemp and Cannabinoids Department and Federal and International Law Group. She helps cannabis, hemp, and psychedelics businesses navigate the intersections between state and federal law and ensure compliance as laws evolve. Ms. Hauser's practice focuses on regulatory compliance, licensing, general business representation, policy reform and strategic guidance to best position businesses for success at the at state, national, and international levels. With more than a decade of experience in cannabis law and policy, Shawn is a go-to source for businesses, industry groups, governments, and reporters seeking opinions, analysis, and guidance. She has presented on cannabis law and policy to many local, federal, and international agencies, including the U.S. Food and Drug Administration and UK Parliament. As an equity partner, Ms. Hauser risks criminal liability and the loss of her license to practice law for her work and the work of the firm as a whole. She also faced substantial barriers when seeking a home loan, and she has endured tangible social stigma in the legal and broader social community due to her involvement with cannabis clients. Ms. Hauser wishes to participate at the December 2, 2024, hearing in person; she is also willing to provide written testimony if her in-person participation at the hearing is not granted by DEA.

Accordingly, Vicente LLP submits this filing to participate to the fullest extent permissible by law in any hearing relevant to this rulemaking that DEA grants. Vicente LLP is an Interested Person because the Proposed Rule, if finalized, would adversely affect and aggrieve Vicente LLP, both directly and indirectly through the existence of, and revenues generated by, its clients' businesses.

Put simply, the Proposed Rule, if finalized, would directly and adversely affect Vicente LLP and its clients. Vicente LLP needs to show only administrative standing, rather than Article III standing, to participate in this administrative proceeding. *Animal Legal Def. Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 21 (D.D.C. 2017) (discussing a lower threshold required for "administrative

standing" compared to Article III standing). But regardless, for all the reasons just described, Vicente LLP has standing under both standards. Broad participation in agency proceedings and an expansive understanding of the term "Interested Person" are often necessary because the agency's decision-making implicates public policy. Id.

E. No Basis Exists to Deny Vicente LLP's Participation in the Hearing

No basis exists to deny Vicente LLP's participation if DEA convenes a hearing. In fact, none of the reasons courts have cited to deny a movant's participation in an administrative proceeding apply here. *See Nichols v. Bd. of Trustees of Asbestos Workers Loc. 24 Pension Plan*, 835 F.2d 881, 897 (D.C. Cir. 1987). Collecting cases, the D.C. Circuit noted that courts had denied participation when (i) other parties to the proceeding adequately represent the would-be participant's viewpoint; (ii) participation would broaden unduly the issues considered or obstruct or overburden the proceedings; or (iii) participation would fail to assist the agency's decision-making. Id.

First, no other participant in the rulemaking would adequately represent Vicente LLP's viewpoint.[9] Vicente LLP has interests in the rulemaking proceedings distinct from those of DEA. Vicente LLP possesses a unique understanding of the U.S.' ability to place marijuana outside of schedule I of the CSA while simultaneously complying with international treaty obligations, among other topics.

Second, Vicente LLP's participation would not unreasonably broaden the issues under consideration in the Proposed Rule or obstruct proceedings. DEA has sought information on the practical consequences of rescheduling. Vicente LLP is prepared to provide that perspective at the hearing. Vicente LLP would abide by the requirements and briefing standards applicable to other participants in the formal rulemaking procedure.

Third, Vicente LLP's participation would benefit the agency's decision-making process. As noted above, Vicente LLP's unique perspective would provide insight into: (i) the appropriate schedule for marijuana;[10] (ii) the U.S.' ability to reschedule (or de-schedule) marijuana while remaining compliant with its international treaty obligations;[11] (iii) the practical consequences of rescheduling marijuana under the relevant statutory and regulatory frameworks;[12] and (iv) state medical marijuana programs, particularly as they relate to the harms that program participants (i.e. patients and medical professionals) face with marijuana in schedule I.

For all these reasons Vicente LLP hereby requests the ability to participate in the rulemaking process to the fullest extent permissible by law and participate in the December 2, 2024, hearing.

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[9] While this filing is made without knowledge of other participants in the potential ALJ hearing, Vicente LLP provides a unique perspective that would not be cumulative to or adequately represented by other participants if DEA grants a hearing on the Proposed Rule.
[10] *See Supra,* Note 2.
[11] *See Supra,* Note 3.
[12] *See Supra,* Note 4.

Vicente.

All notices and correspondence to be sent pursuant to this appearance should be addressed to me at the address provided below.

Respectfully yours,

/s/ Timothy D. Swain
Timothy D. Swain
Vicente LLP
800 Boylston Street, 26th Floor
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Shawn Hauser
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1553 Platte St. Ste. 310
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Jason Adelstone
Vicente LLP
1553 Platte St. Ste. 310
Denver, CO 80202
J.Adelstone@VicenteLLP.com

Enclosures:

- Exhibit A: Declaration of Shawn Hauser
- Exhibit B: Declaration of Jason Adelstone

Vicente.

Exhibit A
Declaration of Shawn Hauser

(attached)

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 **Docket No. DEA-1362** **Currently scheduled for December 2, 2024, at 9:00am E.T.**	**EXPERT WITNESS DECLARATION OF SHAWN HAUSER**

EXPERT WITNESS DECLARATION OF SHAWN HAUSER

I, Shawn Hauser declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I could and would competently testify to the matters stated herein.

2. I am a Partner with the law firm, Vicente LLP.

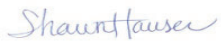
3. I have specialized in cannabis law and policy for 13 years. I attended law school at the University of Denver Sturm College of Law, where I clerked for a cannabis focused law firm (McAllister, Darnell, & Gottleib), led the law school's NORML Chapter, and volunteered with Sensible Colorado, a patients advocacy organization. Since graduating law school in 2011, my legal practice has specialized in cannabis law and policy, including having a leading role in shaping and implementing medical and adult-use cannabis regulations in Colorado at state and local levels. I have been at the firm Vicente LLP for 11 years, where I am a managing equity partner and chair our firm's Hemp and Cannabinoid Practice, as well as the Federal and International Law Practice. My practice focuses on state medical marijuana and adult-use marijuana and hemp regulatory programs, including but not limited to legal considerations, regulatory frameworks, the interplay between federal and state laws, and the unique challenges of patients, doctors, researchers, businesses, and other stakeholders. Throughout my time as associate and partner at VLLP, I have specialized in state cannabis regulatory frameworks and counseled clients (from doctors, patients, businesses, to researchers and governments) relating to the same. In addition, over the past 6 years, I have studied the application of international drug treaties to US cannabis laws and have studied under leading international policy experts.

4. No other party to these proceedings will adequately represent my viewpoints.

5. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 26, 2024.



Shawn Hauser, Esq.
1553 Platte St Suite 310,
Denver, CO 80202
s.hauser@VicenteLLP.com
303-860-4501

Vicente.

Exhibit B
Declaration of Jason Adelstone

(attached)

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 **Docket No. DEA-1362** **Currently scheduled for December 2, 2024, at 9:00am E.T.**	**EXPERT WITNESS DECLARATION OF JASON ADELSTONE**

EXPERT WITNESS DECLARATION OF JASON ADELSTONE

I, Jason Adelstone, declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I can, and will, competently testify to the matters stated herein.

2. I am a Senior Associate with Vicente LLP, a national cannabis law firm, and I co-chair our firm's Federal and International Practice Group.

3. Over the past six years, I have worked closely with leading international drug treaty experts from around the world, and I regularly provided guidance, on member states' (including the U.S.') obligations under the three international drug treaties to U.S. agencies, foreign government officials, the International Narcotics Control Board, and marijuana businesses.

4. I am a leading authority on U.S. on international cannabis policy.

5. Along with other international cannabis policy leaders and leading drug treaty scholars, I have participated in expert forums on the obligations of member states under the three international drug treaties – most recently in Amsterdam, Netherlands.

6. I will provide relevant information, which will assist DEA's decision-making, on the U.S.' obligations under the three international drug treaties, particularly as they are implemented through the Controlled Substances Act, and DEA regulations related thereto.

7. I am also able to provide an in-depth review of future DEA regulations that must be promulgated to fill the modest gap in international treaty compliance that will result from marijuana being moved outside of schedule I.

8. No other party to these proceedings will adequately represent my viewpoints.

9. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 26, 2024.

Jason Adelstone, Esq.; M.B.A.
1553 Platte St Suite 310, Denver, CO 80202
j.adelstone@VicenteLLP.com
720-310-3136

September 29, 2024

Drug Enforcement Administration,
Attn: Hearing Clerk/OALJ
600 Army Navy Drive, Arlington, VA 22202

Subject: Notice of Appearance

Dear Sir:

Please take notice that Kai Hoffman will appear in the matter of: DEA Cannabis Rescheduling Hearing - December 2, 2024.

(A) I am appearing in this proceeding as a cannabis industry expert, author of America's first cannabis utility patent, and a representative of citizens and businesses advocating for the fair rescheduling and regulation of cannabis. My interest lies in ensuring the rescheduling of cannabis is carried out based on factual data and scientific integrity, with a focus on genetic authenticity and proper regulation akin to alcohol and tobacco.

(B) I object to the proposed rescheduling of cannabis to Schedule III, as it remains inconsistent with the evidence of its medicinal properties and imposes unwarranted restrictions. I also object to the use of flawed, unscientific data and high-THC narratives, which have been perpetuated by parties with vested economic interests in preventing widespread cannabis acceptance. I desire to be heard on issues of genetic authentication, constitutional rights violations, and the need for comprehensive, fair regulation of cannabis.

(C) I hold that cannabis should be removed from the Controlled Substances Act entirely, regulated like alcohol and tobacco under an honor system where users are treated with respect and fairness. The Schedule III classification does not adequately serve the interests of patients, researchers, or the economy and is instead being driven by biased and unconstitutional interests. I am here to present data and arguments that reflect the true medicinal, economic, and social benefits of cannabis, and to advocate for its proper recognition and regulation.

All notices to be sent pursuant to this appearance should be addressed to:

Kai Hoffman
610 Burley Road
Annapolis, MD 21409

Respectfully yours,

Kai Hoffman

443-926-1570
Strainj

Subject: Request to Participate in the Hearing on Proposed Rescheduling of Marijuana (Docket No. DEA-1362)

Comment on FR Doc # 2024-11137
Posted by the Drug Enforcement Administration on Jul 21, 2024 & Jul 23, 2024

https://www.regulations.gov/comment/DEA-2024-0059-35675

https://www.regulations.gov/comment/DEA-2024-0059-40210

Agency: Drug Enforcement Administration Department of Justice
Date: September 29, 2024
From: Kai Hoffman
Address: 610 Burley Rd, Annapolis, Maryland, 21409

Dear Administrator Anne Milgram and the DEA Team,

Introduction and Interest in the Proceeding:

I am requesting to participate in the upcoming hearing on December 2, 2024, regarding the proposed rescheduling of marijuana. My interest in this proceeding is to eliminate cannabis from the Controlled Substances Act (CSA) entirely and regulate it similarly to alcohol and tobacco. My data is instrumental in correcting misconceptions about cannabis' effects, and the current classification is based on incorrect assumptions about THC as the primary factor. Cannabis is about the balance of cannabinoids, and I intend to show why it should be more accessible, safer, and appropriately regulated for the benefit of public health.

Basis for Request:

1. Political Manipulation, Lobbying, and Discriminatory History:
The Alcohol, Tobacco, Firearms, and Explosives (ATF) should include cannabis, as it is a substance that has more in common with alcohol and tobacco in terms of societal use, effects, and regulation potential. However, political manipulation and corporate lobbying have actively suppressed this, creating a regulatory framework that unfairly criminalizes a substance proven to have significant medical benefits and a lower risk profile compared to the substances that ATF currently manages.
The CSA has been misused from its inception, not as a genuine protective measure for the public but as a tool for social and political control. The Nixon administration's overtly racist and anti-counterculture motivations were rooted in maintaining power. John Ehrlichman's statements are not merely reflective of the past—they serve as a blueprint for continued misuse of drug policy for social manipulation.

Ehrlichman stated:
"The Nixon campaign in 1968 and the Nixon White House after that had two enemies: the antiwar left and Black people. You understand what I'm saying? We knew we couldn't make it illegal to be either against the war or Black, but by getting the public to associate the hippies with marijuana and Blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did."

In addition to the racially motivated arrests, Big Tobacco was advertising seven times more in low-income Black neighborhoods, further contributing to the oppression of these communities by promoting one of the most addictive substances while locking them up for seeking safer alternatives like cannabis. Meanwhile, the CIA was responsible for creating the crack epidemic by selling cocaine to American citizens, tearing apart communities at large. The CIA also did the same during the Afghan-Russian war, selling weed to fund weapons purchases with untraceable cash. This same tactic was applied during the 1980s cocaine epidemic, which fueled and created the crack epidemic for the same purpose: raising untraceable funds. THE GOVERNMENT IS THE SUPPLIER & NARC

These injustices reflect a systemic plan to oppress and profit from marginalized communities through controlled substances. The bribery disguised as lobbying from Big Tobacco, Big Alcohol, Big Pharma, and Big Agriculture is indicative of an agenda to maintain control over recreational substances, regardless of the cost to public health. These industries see cannabis as a substitute good that competes with their products, which explains the heavy resistance to legalization.

Steve D'Angelo, owner of Steep Hill Labs, has played a problematic role in the cannabis industry, particularly in perpetuating the misrepresentation of THC. D'Angelo is partially responsible for creating the THC-centric narrative that has limited the broader understanding of cannabis. This misrepresentation played a role in the DEA's reluctance to reschedule cannabis, as they were misled into believing THC was the sole defining component of cannabis' effects, neglecting the importance of other cannabinoids and the entourage effect.

Steve D'Angelo's own top scientist at Steep Hill Labs, Reggie Gaudino, who owns the world's largest genetic database on cannabis, has declared that the cannabis we currently have is extinct in its original form and that it is possible to reset the genome. Despite having access to this information, Steve has been searching the globe frantically for authentic genetics while slow rolling our progress and misrepresenting our ruthless business plan to protect his interests. He has kept the original medicinal cannabis away from customers because he cannot personally profit from it, and our business model threatens his investments, such as his dispensary brand, Harborside.

Furthermore, the DEA has been neglecting the importance of genetic authenticity between the hemp species and drug species of cannabis, which is also Steve D'Angelo's fault, as he blurred these lines while being part of a group that included Marijuana Botany author Robert Connell Clarke, who was a significant hemp advocate. Clarke worked with GW Pharmaceuticals, which created a CBD patented product called Epidiolex, and also collaborated with "Sam the Skunk Man," who was allegedly a government informant and possibly a CIA operative, as well as Todd McCormick. All of these individuals were responsible for breeding hemp into the cannabis genome while subsequently claiming to be "grandfathers and founders of legacy cannabis," a claim that misrepresents their true role in diluting the medicinal genetics of the plant. These individuals might also be responsible for a conspiracy to spread hemp pollen within the cannabis genetic populations because they are either feds or they got caught, and destroying the original drug plant genome may have been part of their plea bargain deal.

2. Nicotine vs. Cannabis – Receptor Differences and Navy SEAL Example:

Nicotine is the most widely used psychoactive stimulant in the world, yet it is also the most addictive and harmful legal substance. Given the graphs and details shown in my DEA comments, nicotine is also the top killer of all drugs in America and the world. The nicotinic acetylcholine receptors (nAChRs) are found throughout the central and peripheral nervous systems, and they regulate various functions, including muscle contraction and cognitive processes. Nicotine's activation of these receptors leads to a powerful

release of dopamine, causing the intense addictive properties that make it incredibly difficult for users to quit. It is also directly linked to cardiovascular disease, respiratory issues, and numerous forms of cancer.

My experience with Navy SEALs, using Siberian tobacco bags and Copenhagen long-cut wintergreen, underscores nicotine's profound and dangerous impact. These elite soldiers—trained to withstand intense physical and mental strain—would purposely floor themselves with nicotine because there is a nicotine receptor in every single muscle in the body, making nicotine extremely addictive. Being "floored" meant that they would become extremely sedated, allowing them to relax from stress. Doing high amounts of nicotine would provide a sense of narcotic relief, similar to how opioids can induce a sense of euphoria and relaxation.

Unlike nicotine, cannabis is not as potent and does not cause the same level of complete physical sedation. While nicotine can sedate every muscle in the body to the point of making a person feel "floored," cannabis works by modulating neurotransmitter activity without causing such extreme effects. Nicotine causes every single muscle in the body to vibrate intensely, creating a sensation similar to levitating, which is akin to the dissociative effects of ketamine. Ketamine works along the glutamate receptors in the human brain and body to cause sedation. However, in the case of nicotine, sedation occurs within the physical muscles themselves, making it far more toxic and harmful than cannabis. Nicotine's widespread impact on muscle receptors, leading to physical sedation and dependency, highlights its toxicity compared to the more selective and balanced effects of cannabis.

For individuals with ADHD, cannabis offers a safer and less addictive alternative to traditional stimulant medications. Studies have shown that when individuals with ADHD are properly prescribed medication that stops them from "dopamine seeking," they have a 70% reduced chance of abusing cocaine. In the face of the ongoing fentanyl crisis, it is vital that we provide real, authenticated, old-school medical cannabis to the market. Personally, I have lost two friends who were not properly prescribed medication and ended up overdosing on fentanyl-laced cocaine. In another instance, I saved a friend's life using Narcan after they were drugged at a concert; the fentanyl turned his skin green, and after Narcan application, his stomach and bowels released, indicating an opiate overdose. If proper herbal medicine had been available, these tragedies could have been avoided, and my friends might still be alive.

3. Hallucinogenic Alcohol from Wormwood:

Absinthe, a hallucinogenic alcoholic beverage derived from Wormwood, is another example of a substance with psychoactive effects that has found a place in the market despite its controversial history. Absinthe contains thujone, a chemical compound that can induce hallucinations, alter perception, and affect the central nervous system. For years, absinthe was banned and vilified for its supposed dangers, yet it is now legal and available under regulatory oversight. This shows that substances with psychoactive properties can indeed be safely managed when proper regulations are in place, underscoring the inconsistencies in current substance control laws.

Unlike absinthe, cannabis has never been linked to a fatal overdose and has been used for thousands of years for both recreational and medicinal purposes. Despite its superior safety profile, cannabis continues to be highly restricted, while a substance like absinthe—which poses a greater risk of toxicity and alcohol poisoning—has been legalized. This regulatory discrepancy highlights the double standard in the classification of psychoactive substances and the outdated misconceptions that still surround cannabis. If absinthe, a hallucinogenic drink, can be integrated into society with appropriate regulation, cannabis, which has an even better safety and therapeutic profile, should be given the same treatment.

Thujone, the psychoactive compound in absinthe, affects the GABA receptors in the brain, producing effects that include hallucinations and altered consciousness. The regulation of absinthe demonstrates that substances which interact with the nervous system in profound ways can be managed within a legal framework that prioritizes education and moderation. The approach taken with absinthe provides a clear precedent for how cannabis should be regulated. While absinthe is marketed as an exotic drink with an element of risk, cannabis, with its medicinal properties and non-toxic nature, is still classified as Schedule I, implying it has no medical value and a high potential for abuse—both of which have been scientifically disproven.

The legalization of absinthe is a testament to the power of lobbying and economic influence in determining what substances are allowed in the marketplace. The alcohol industry has successfully marketed absinthe as a sophisticated, high-end drink, despite its history of misuse and potential for neurotoxicity. Cannabis, on the other hand, has faced stigmatization rooted in political manipulation and corporate interests that sought to suppress its widespread use due to the threat it posed to Big Tobacco, Big Pharma, and Big Alcohol. The narrative around cannabis has been intentionally shaped to instill fear, despite the evidence of its therapeutic benefits and non-toxic nature.

Wormwood-derived absinthe was eventually legalized after being glamorized in popular culture and marketed as an exotic luxury, despite having psychoactive properties similar to other controlled substances. Cannabis, which does not have the same level of risk associated with hallucinogenic compounds like thujone or the risk of respiratory failure that comes with alcohol, has been treated far more harshly under federal law. The inconsistencies in how these substances are classified and regulated speak to an ongoing bias and double standard within the system, one that needs to be addressed in order to bring cannabis regulation in line with modern scientific understanding.

Additionally, absinthe's journey from being a banned substance to becoming a regulated product demonstrates that societal acceptance and regulation are possible for substances with a history of controversy. With absinthe, the risks were mitigated through proper labeling, consumer education, and responsible production, paving the way for its reintroduction into society. Cannabis, however, has faced barriers that have less to do with its inherent properties and more to do with a manufactured stigma created by corporate interests that saw it as a threat.

The history of absinthe and its eventual acceptance as a regulated product serves as a model for how cannabis should be treated. Despite having psychoactive effects, absinthe is now legally sold and even embraced in certain circles as a part of culinary and cultural experiences. Cannabis, with its ability to provide relief for a wide range of medical conditions and enhance quality of life without the same level of risk, should not be criminalized and kept out of reach for millions of Americans who could benefit from it. If a substance like absinthe can be legally regulated, then the classification of cannabis as a Schedule I drug is not only scientifically inaccurate but also fundamentally unjust.

4. Genetic Superiority – Cannabis Hybrid ADAM:

The genetic history of cannabis has been marked by dilution and misinformation. The introduction of hemp genetics into cannabis, presented as a means of making cannabis "legal," ultimately reduced the medicinal efficacy of available strains. Today's commercial cannabis is often unstable, with inconsistent cannabinoid content, leading to unpredictable effects and diminished therapeutic value. This instability has led to a focus on high THC content at the expense of other cannabinoids, resulting in strains that are imbalanced and more likely to produce negative side effects such as anxiety and paranoia.

The patent that we are debunking, US Patent 9095554, claims the need for cannabis varieties that produce modulated THC concentrations along with other pharmacologically active substances to reduce negative side effects and increase medicinal benefits. On Page 22, Section 2, the patent mentions how THC concentrations have increased, making legalization more difficult, and claims a need for healthier cannabis for both recreational and medical use with reduced negative side effects from THC. It is incorrect on many levels because it continues to focus solely on THC, disregarding the importance of other cannabinoids, flavonoids, and the entourage effect. Moreover, Robert Connell Clarke stated that the best cannabis has 15% THC—a balanced level suitable for medical purposes. However, the patent implies that lower THC concentrations are better for medicinal use without providing an ideal range, adding to the confusion. Our Cannabis Hybrid ADAM directly meets the ideal THC percentage under NORML's standards, allowing space for other cannabinoids to contribute to a more therapeutic effect. We solve the problem that Patent 9095554 states by offering modulated THC and stable cannabis strains that are consistent in morphology and chemical composition.

Cannabis Hybrid ADAM restores genetic stability by using advanced breeding techniques like backcrossing, pedigree breeding, and molecular marker analysis. These methods stabilize the genetics to ensure that each plant consistently expresses a balanced combination of THC, CBD, THCV, and other cannabinoids, resulting in effective medicinal outcomes. Unlike other unstable commercial strains, Cannabis Hybrid ADAM maintains genetic consistency across every generation.
As Cannabis Hybrid ADAM is genetically authentic, it holds hierarchical rights over other cannabis varieties. This means that our authentic and stable genetics set the standard for cannabis research and products. Much of the existing scientific research needs to be redone because it was based on genetically inconsistent plants. This is a standard that applies to other industries as well—tobacco, agricultural products, and alcohol must meet strict authenticity requirements, and cannabis should be no different. The current inconsistency also violates Section 502 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which mandates accurate product representation.

Our work involves restoring genetic stability through authentic original genetics, bypassing modern hybrids diluted by hemp. Dr. Reggie Gaudino, leader at Steep Hill Labs, owns the largest cannabis genetic sequencing database. His research has demonstrated that many of today's strains have genetic ties to cultivars preserved from 20-30 years ago. By comparing these genetics with today's plants, Gaudino showed the feasibility of restoring the original genome, allowing patients to experience the entourage effect—a synergistic interaction of cannabinoids, flavonoids, and other compounds that enhances therapeutic outcomes.

Steve D'Angelo, owner of Steep Hill Labs, has access to this genetic data but has been slow rolling progress and misrepresenting our business plan to protect his interests, including his dispensary brand, Harborside. Our Cannabis Hybrid ADAM would undermine his control over the market by making authentic medicinal cannabis widely available. Unlike D'Angelo's approach of keeping genetics inaccessible, our mission is to reset the cannabis genome and provide patients with reliable, consistent, and potent medicine.

The modulated cannabinoid profiles in Cannabis Hybrid ADAM provide a balanced combination of THC, CBD, THCV, and other cannabinoids. The inclusion of THCV, for example, helps counteract THC-induced appetite stimulation, making it suitable for individuals managing weight or conditions like diabetes. Our approach ensures genetic integrity, offering medicinal cannabis that is predictable and effective, minimizing adverse reactions.

Additionally, the genetics of Cannabis Hybrid ADAM include traits that enhance plant resilience, improve yield, and ensure consistent production. This stability means that patients receive a uniform product with every batch, eliminating the variability caused by improper breeding and genetic instability. Our focus is on restoring the natural balance of cannabinoids that historically made cannabis an effective medicinal plant. The genetic fingerprinting performed on ADAM also provides a means to license and track IP, preserving cannabis genetics and preventing genetic piracy.

The involvement of individuals like Steve D'Angelo, Robert Connell Clarke, Sam the Skunk Man, and Todd McCormick in the breeding and dilution of cannabis genetics raises serious questions about their motivations. These individuals might also be responsible for a conspiracy to spread hemp pollen within the cannabis genetic populations either as part of their role as federal operatives or due to plea bargains. Their actions have weakened the medicinal potential of cannabis, all while positioning themselves as "grandfathers of legacy cannabis"—a misleading narrative that ignores the significant damage done to the original drug plant genome

5. Terpenes – Olfactory Amygdala Memory Response:

The discussion around terpenes has been fundamentally misunderstood, especially in the patent being debunked, which incorrectly claims that terpenes are responsible for the psychoactive effects of cannabis. In reality, terpenes are aromatic hydrocarbons that contribute to the olfactory experience of cannabis, interacting with the amygdala—the part of the brain responsible for emotional processing and memory formation. This response is similar to smelling something that triggers a flashback to childhood, such as the smell of a grandparent's house.

Terpenes are chemical responses to olfactory stimuli, not a drug effect. They create chemical illusions that produce a memory-based response, which can create a meditative vibe akin to how essential oils can deepen meditation. However, there is no pharmacological drug reaction involved—terpenes do not interact with the endocannabinoid system in a way that produces psychoactive effects, the way flavonoids and cannabinoids do. Their role is to enhance the emotional and sensory experience rather than directly impact the therapeutic effects of cannabinoids.

Arrests and legal charges based solely on the smell of terpenes are scientifically unfounded and unconstitutional. Terpenes are non-psychoactive and are present in many plants, fruits, and herbs. Using their scent as evidence of illegal cannabis possession is a misunderstanding of plant biology and olfaction, leading to unjust actions. This issue underscores the urgent need for educational reform among law enforcement involved in cannabis-related policing to prevent abuses based on misinformation.

The emphasis on terpenes as key drivers of cannabis effects has been heavily overstated in cannabis marketing, leading to confusion. The true therapeutic effects of cannabis come from the cannabinoid profile and the entourage effect, involving cannabinoids and flavonoids. Our work with Cannabis Hybrid ADAM focuses on genetic authenticity and a consistent cannabinoid and flavonoid profile, which are the real contributors to therapeutic benefits.

6. Unconstitutional Arrests and Lawsuits:

My illegal federal arrest violated the Fourth Amendment, as the charges were based solely on the smell of terpenes—an entirely unfounded basis for legal action since terpenes are not controlled substances—nor ever will be, because they are not drugs, plain and simple. This case is just one example of a broader systemic issue within cannabis law enforcement, which continues to rely on outdated and scientifically incorrect assumptions rather than evidence-based practices. The use of terpene scent as a basis for search and seizure is an illusion and a manipulation tactic, especially prevalent when racially profiling individuals. Terpenes, which can be found in oranges, essential oils, and many plants, fruits, and herbs, are not drugs, and using their scent as a basis for legal action is a clear violation of constitutional rights. I experienced this firsthand during an encounter with a Navy federal officer from Chicago, who ignored Maryland law regarding cannabis, enacted in 2023. Shortly afterward, the legal deep state system became apparent as Illinois lawmakers announced that they would no longer use the smell of cannabis as probable cause for search and seizure—a decision likely aimed at covering up the misconduct involving their Chicago resident. This incident is not isolated, as I am currently pursuing lawsuits against the Navy and the Maryland Police Department for similar abuses, including the fabrication of charges following this illegal arrest.

Furthermore, I am pursuing lawsuits against Equinox Gym, which is connected to the GOP and complicit in my experiences of sexual battery and community stalking (and is known to be a big donor to the GOP). The GOP and conservative political interests are intertwined with entities like Equinox, the ATF, and the DEA, and they have been aware of my activities in the cannabis space for a long time. When I provided Equinox with employment information—stating that I authored America's first cannabis utility patent in partnership with my business associate—this information was entered into their system. This led to a targeted campaign against me, resulting in sexual battery, community stalking in Los Angeles, and ongoing harassment designed to silence and intimidate me as a cannabis advocate.
The GOP's influence and their connection to law enforcement agencies like the ATF and DEA highlight the broader political motivations behind these acts of harassment and abuse. This systemic targeting is an attempt to maintain control over cannabis reform efforts, undermining progress and intimidating those who are pushing for change. The involvement of Equinox in these actions, and their collaboration with these political entities, underscores the larger network of systemic injustice that continues to impede cannabis reform and the personal freedoms of individuals involved in this industry.

Additionally, several individuals have intentionally worked together to undermine my efforts, cause harm, and sabotage my business. Steve D'Angelo played a significant role in slow-rolling my progress, manipulating me, and ultimately contributing to my PTSD and permanent teeth chattering (known as bruxism). I also suffer from hypersomnia, causing constant exhaustion despite adequate sleep. Alongside him, California's attorney "Mr. Prop 64" Khurshid Khoja (#233866) intentionally sabotaged our deals and failed to meet his obligations, deliberately causing significant financial damage to us because all his clients are our competitors, such as the Cookies brand. This is clear malpractice, and he will be disbarred, as I have all the documentation to prove his manipulation ready on deck. These individuals have worked to block deals and sought to undermine my company by attempting to gain access to our cannabis utility patent.

Our business plan is ruthless because it is based on original genomes and DNA—a strategy akin to that of Coca-Cola and Monsanto. Our approach cannot be replicated because it involves a plant and takes advantage of a loophole in American law that allows for pure monopolization. Our company is technically in the biopharmaceutical industry, and our impact will extend across the four largest industries that have lobbied against cannabis for over a century: Big Tobacco, Big Alcohol, Big

Pharmaceutical, and Big Agriculture. These industries have engaged in what they call "lobbying," but in reality, it is bribery—influencing the DEA, the Controlled Substances Act (CSA), and the Federal Food, Drug, and Cosmetic Act (FDCA). The economic corruption in America is significant, with the country ranking 30% on the global economic corruption scale.

These lawsuits are part of a broader effort to expose and correct the systemic injustices that have plagued cannabis regulation and enforcement for decades. The targeting of cannabis advocates, entrepreneurs, and users is not new; it is a continuation of the discriminatory tactics used during the original "War on Drugs". These unconstitutional actions must be addressed and corrected, not just for myself but for the countless others who have faced similar targeted harassment and rights violations. The search and seizure practices used by law enforcement, based on the smell of terpenes, have been the "go-to" tactic for manipulation for years. The reliance on olfactory evidence that is scientifically unfounded represents a significant abuse of power, one that must be addressed through legal channels and educational reform among law enforcement officers. It is crucial to eliminate these discriminatory practices and create a fairer legal system that respects constitutional rights and scientific evidence.

7. Cannabis as a Regulatory Medicine, Not a Controlled Substance:

Cannabis must be removed from the Controlled Substances Act (CSA) and instead regulated similarly to alcohol and tobacco. The current Schedule I classification is scientifically incorrect, ignores its medicinal potential, and prevents critical medical research. Cannabis has been proven effective in treating chronic pain, epilepsy, PTSD, anxiety, ADHD, and even neurodegenerative diseases like Alzheimer's and multiple sclerosis, and many more that I am sure everyone is aware of. Its interaction with the endocannabinoid system is unique and unmatched by any synthetic drug, underscoring its value as a regulatory medicine rather than a controlled substance.

The ongoing efforts by Conservatives, GOP members, and others involved in lobbying to slow down the rescheduling process are both unconstitutional and detrimental to public health. These individuals, working in conjunction with industries like Big Tobacco, Big Alcohol, Big Pharmaceuticals, and Big Agriculture, have a vested interest in preventing cannabis from becoming widely accepted. Their actions have led to a rescheduling proposal to Schedule III, which does not adequately address the barriers to research, patient access, and economic development that persist with any classification under the CSA. It was because of my data and low THC genetically authenticated cannabis that they had to address rescheduling; however, they initially tried to use the false high THC narrative to avoid making these changes. Can you tell where their interests lie? I am forcing this change myself, for me, my business partner, the American citizens, and the economy.

Even the research conducted under the Schedule I classification is fundamentally flawed. My hierarchical genetic data reveals that prior research has been conducted without proper genetic authentication of the cannabis plant being studied. This means that the findings are inconsistent and effectively retracted, as the researchers had no way of knowing what plant they were actually studying. The fake THC science promoted by those with economic interests in keeping cannabis illegal has further hindered progress. The American economy was manipulated to maintain this false narrative, with lobbying from tobacco, pharmaceutical, alcohol, and agriculture industries.

Our genetically authenticated cannabis provides the foundation for proper studies, allowing for the creation of evidence-based regulations. Keeping cannabis in Schedule I based on outdated, unscientific

data is unconstitutional and violates Section 502 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Those who have lobbied to keep cannabis illegal and who have profited off of hemp rope and other misrepresented products must be held accountable, as these actions defraud consumers and violate federal law. I am commanding a full country-wide economic genetic authentication regulation of cannabis. Without this regulation, lawsuits will arise, as customers are being sold products that are not what they claim to be. The modern bastardized hybrid plants have too many side effects because they mutated, while humans did not evolve with these plants.

The slow-rolling of the rescheduling process by conservative lawmakers and industry lobbyists is part of a broader strategy to insert themselves into cannabis companies for personal profit, which is a blatant violation of public trust and unconstitutional. Through my deep state connections, I have learned that this intentional delay benefits those seeking to profit at the expense of public health and justice. Furthermore, the misuse of cannabis by law enforcement officers has been a common practice and still is in many parts of the United States. I have names that I will drop in Maryland, specifically Anne Arundel County, which could significantly affect these officers' pension plans. How can a system be so racist, unjust, and bigoted that officers are double dipping—seizing cannabis from people, consuming it themselves, and then arresting others while under the influence? How could an Anne Arundel County cop ask me how I functioned under the influence of my medicine that stopped my stuttering, relieved my chronic scoliosis pain, and helped with my ADHD, when cops themselves have been operating high for decades? Why don't you ask yourself how you are able to do this?

Unfortunately, most of these officers were white and used these tactics as racial population control and gerrymandering to fill the privatized jail system—the gangster's paradise. This has been a common practice among officers since the 1970s, and yes, you all know this is true. Do not lie to my face, you hypocrites.

Cannabis should be regulated similarly to tobacco and alcohol, where the policy is practically based on user discretion and an honor system. Unlike alcohol, cannabis does not intoxicate the blood, as it is not an alcohol-based substance. Instead, it is far more similar to tobacco, where, if a user is too "floored" or sedated by tobacco bags or products, it is clear that they should not drive. The same principle applies to cannabis, making its regulation akin to that of tobacco much more appropriate and rational.

The regulation model should follow examples such as Florida, where cannabis is integrated into mainstream commerce safely. Cannabis products, such as cannabis cigarettes, are available in grocery stores and gas stations that have obtained the necessary licenses—similar to the requirements for alcohol and tobacco. This is why the ATF should be dismantled and restructured as the ATFC (Alcohol, Tobacco, Firearms, Explosives, and Cannabis).

Moreover, the paradoxes in current substance regulation are apparent: substances like alcohol and tobacco are allowed, despite their well-documented intoxicating effects and risks, such as tobacco dip bags causing people to get floored or excessive alcohol consumption impairing the ability to drive. Meanwhile, cannabis, which poses far fewer risks, remains restricted. This inconsistency demonstrates the irrational and harmful nature of current policy and underscores the urgent need for reform.

Conclusion:

I am requesting to participate in this hearing to present data and arguments that challenge the current narrative around cannabis. The rescheduling of cannabis to Schedule III does not go far enough; instead, cannabis should be regulated similarly to alcohol and tobacco, effectively removing it from the CSA altogether.

My data has forced this reconsideration, and it is crucial that cannabis is recognized for its medical, economic, and social benefits without being restricted by an outdated classification. I look forward to further discussing these matters at the hearing on December 2, 2024.

Respectfully,
Kai Hoffman

https://finance.yahoo.com/news/flower-power-genetics-secures-pending-123000289.html

Outlook

[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Kainan Boring <kainanmatthew@icloud.com>
Date Sun 9/29/2024 1:45 PM
To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

While I acknowledge the proposed rescheduling, I firmly believe that marijuana should be descheduled entirely. My interest in this proceeding stems from the following points:

1. The medical benefits of marijuana and its potential to improve the quality of life for many patients, especially those who are incarcerated and suffer from health issues exacerbated by their imprisonment. Rescheduling could inadvertently reinforce the stigmatization of marijuana as a political tool rather than recognizing its therapeutic properties.
2. The importance of acknowledging the long-standing impact of marijuana prohibition on marginalized communities, leading to mass incarceration and injustice. Descheduling marijuana would be a crucial step toward rectifying these historical wrongs and alleviating the burden on those who are currently imprisoned for marijuana-related offenses.
3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.

I appreciate the opportunity to participate in this important discussion.

Sincerely,

Sent from my iPhone

,September 29, 2024

Drug Enforcement Administration, Attn: Administrator
Subject: Notice of Appearance
8701 Morrissette Drive, Springfield, VA 22152

Dear Administrator,

Please take notice that I, **Keila Castillo**, will appear in the matter of: Proposed Rescheduling of Marijuana (Docket No. DEA-1362).

I am an **advocate and proponent** for cannabis descheduling, representing a community of patients, parents, women, and latine in cannabis through my business, communities, and personal life.

With regard to my business, Creatively Cannabis, which is based out of Denver, CO, I've experienced many changes over the years, especially where regulations and regulatory restrictions have been imposed. Because of scheduling and stringent regulations (as well as a biased system which tends to penalize the entire industry for the complaints of one person), the cannabis events in Denver, which once abundantly-drove both local and tourism money to the state via it's thriving embodiment of community, has nearly dwindled to a trickle of its former glory. "And why is this?" one might ask. Because, unfortunately, a plant with clearly demonstrated medicinal benefit, which has no verifiable track record of causing death or inducing aggression, is being regulated more strictly than alcohol. Alcohol–a substance with some arguable benefits, which has been linked to hundreds of thousands of deaths **each year** with statistics showing that alcohol-related deaths have been on the rise since before 2020 and have continued to increase each year, yet alcohol remains descheduled while cannabis businesses, patients and communities continue to have to fight for access to one of the least statistically-harmful/statistically-habit-forming medicinal substances in use in the US today.

Unfortunately, the reality remains that it's not just the businesses that suffer because of scheduling of marijuana (MJ). The communities, both locally and digitally, suffer unduly because of these unnecessary restrictions. On a local, tangible level, people are prevented, even in legalized states, from consuming outside of their own home–with legislative hoops for consumption sites often being costly, time-consuming, and liable to bankrupt the business before it's even had a chance to open its doors (as has happened multiple times in Denver, including a venue Paint n Play who ended up paying for a lease for a year without ever being able to open since the regulatory board kept finding new reasons to delay the issuance of their consumption permit). **Despite marijuana having been legalized in CO for over a decade, there have never been more than 3 licensed and operating consumption venues at any given time.** And this is to serve a population of over 500,000 legal-aged adults. In what way, shape, or form does that equate regulation consistent to "the manner in which alcohol is regulated"? The obvious answer is that it doesn't. Similarly, in New Jersey, a state which legalized recreational marijuana several years ago, residents are still prohibited from growing their own plants–another capitalistically-hungry move on the part of the government, who refuses to let people cultivate their own plants, despite the relative cost-effectiveness and ease with regard to trying to generate one's own of other

medicine types. This type of legislation is just illusory tactics–where it gives the appearance of making forward progress, but virtually little changes relative to the expectations of the policymakers' constituents.

With regard to digital spaces, law-abiding cannabis and cannabis-adjacent businesses and supporters are continuously fighting with platforms who tend to take a more prohibitive approach to cannabis-related content. This type of censorship, especially the subversive, sneaky, penalty-driven type employed by Meta means that a primary channel and revenue source can be taken down in a millisecond. Imagine, losing YEARS worth of work because you posted ONE thing a robot monitoring content didn't agree with! It's insanity. Other industries (besides maybe adult entertainment) do not face this type of intense scrutiny or overly-harsh punishment and frankly, it violates protected free speech rights. The government's descheduling of MJ would remedy this problem **immediately**.

And while I know the government is eager to earn its share of the massive 420 revenue as has been reported in nearly all legalized states, there are more synergistic/patient-friendly ways to do that. For example, creating a federal plant tax in which a person is taxed a capped number/percentage for each clone bought and each (self-reported?) plant that was not a purchased clone that grew to full harvestable maturation. However, restricting access is not the solution as cannabis has proven to be a self-regulating market if needs aren't met in a legal capacity. In order to get your fair share of an immensely huge pie, the solution is to legalize and impose national federal taxes, with reduced/no taxes on medical (and the ability to have medical MJ either subsidized or covered by health insurance).

With full descheduling, the natural laws of capitalism would help to hone the best businesses and practices–leveling the playing field for communities of color and communities of disability by eliminating unnecessary. bias-demonstrated bureaucracy.

Speaking of minority groups, for me, this is the primary reason I'm such a vocal and tireless advocate for federal legalization/descheduling. As a single, Latine mom who's also disabled, I've had my medicinal cannabis used against me, as have others I know, with regard to eligibility for certain programs (including applying for disability in non-legalized states). Many programs receiving federal funding usually expressly prohibit marijuana use by participants, even if they have a medical marijuana card or live in a recreationally-legalized state. For example, I'm a domestic violence survivor, who, as a result of intensely violent abuse, developed PTSD. Because of the domestic incident, we weren't able to safely go home and, instead had to move into a confidential address shelter, which, due to its federal-funding prohibited MJ despite some scientific (and anecdotal) evidence demonstrating its efficacy for relieving PTSD symptoms including anxiety and insomnia–both self-perpetuating issues as one can cause the other and vice versa.

Additionally, as a disabled person, were I to become eligible for disability-reserved housing or any other type of federally-funded housing stability opportunity, I would be precluded from using the medicine prescribed to me by a licensed physician because of federal restrictions–something that is expressly prohibited in the Americans with Disabilities Act (ADA). Additionally, because of the varied progress of legalization on a national scale, disabled persons using cannabis (as prescribed by a medical

professional) further have their disability rights violated when they're not permitted to travel with or possess their medication with them depending on where within the United States they're traveling–again a violation against a right protected by the ADA.

If we pursue this thought process to disabled persons living in prohibition states (such as South Carolina (SC)), they're **entirely** unable to have the said medication prescribed even if it shows better efficacy for their condition that pharmaceuticals available in their state, thereby discriminating against disabled persons yet again by limiting their access to disability-specific medicines (since at this time all approved cannabis medical conditions can be filed as federally-recognized disabilities). In fact, since cannabis is largely prescribed **specifically** for disability patients, it stands to reason that anything less than **affordable, easily accessible, transparent** national access, regardless of state lines, is a punitive effort against the Disabled community in the US at large.

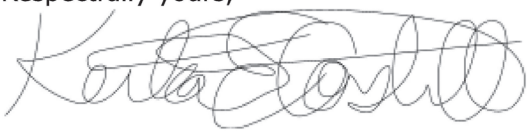
Given that cannabis is less destructive than other Schedule III drugs (looking at you, Xanax) and has less addiction-, aggression-, and death-inducing results than those same schedule III's, it doesn't make sense to lump it in with Xanax (which was taken by someone when they tried to apparently gouge my eye out unprovoked last year…). Additionally, what other Schedule III drug can be deemed safe enough that there are recreational dispensaries? I don't see places where I can pull up and purchase my codeine-based meds. You aren't able to have access to any of these other drugs without a prescription, yet here is MJ which has now been used recreationally in this country with ***NOT EVEN ONE SINGLE MARIJUANA-OVERDOSE OR MJ-OVERDOSE-INDUCED DEATH***.

Thank you in advance for the consideration of my testimony. I hope that the information in my notice would still be taken into consideration even if I'm not selected to appear in the formal hearing.

All notices to be sent pursuant to this appearance should be addressed to:

Kei Castillo
P.O. Box 9120
Chelsea, MA
02150

Respectfully yours,



Outlook

[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Kym Silva <kymsilva31@gmail.com>
Date Sun 9/29/2024 1:07 PM
To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

While I acknowledge the proposed rescheduling, I firmly believe that marijuana should be descheduled entirely. My interest in this proceeding stems from the following points:

1. The medical benefits of marijuana and its potential to improve the quality of life for many patients, especially those who are incarcerated and suffer from health issues exacerbated by their imprisonment. Rescheduling could inadvertently reinforce the stigmatization of marijuana as a political tool rather than recognizing its therapeutic properties.
2. The importance of acknowledging the long-standing impact of marijuana prohibition on marginalized communities, leading to mass incarceration and injustice. Descheduling marijuana would be a crucial step toward rectifying these historical wrongs and alleviating the burden on those who are currently imprisoned for marijuana-related offenses.
3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.

I appreciate the opportunity to participate in this important discussion.

Sincerely,

Kym Silva

Outlook

[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Lilly Tirado <lillycti10@gmail.com>
Date Sun 9/29/2024 10:58 AM
To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

While I acknowledge the proposed rescheduling, I firmly believe that marijuana should be descheduled entirely. My interest in this proceeding stems from the following points:

1. The medical benefits of marijuana and its potential to improve the quality of life for many patients, especially those who are incarcerated and suffer from health issues exacerbated by their imprisonment. Rescheduling could inadvertently reinforce the stigmatization of marijuana as a political tool rather than recognizing its therapeutic properties.
2. The importance of acknowledging the long-standing impact of marijuana prohibition on marginalized communities, leading to mass incarceration and injustice. Descheduling marijuana would be a crucial step toward rectifying these historical wrongs and alleviating the burden on those who are currently imprisoned for marijuana-related offenses.
3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.

I appreciate the opportunity to participate in this important discussion.

Sincerely,

Sent from my iPhone

September 30, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

Subject: Notice of Appearance
Docket No. DEA-1362

Dear Sir:

Please take notice, that ***Chad Kollas, MD, FACP, FAAHPM, HMDC***, on behalf of the American Academy of Hospice and Palliative Medicine (AAHPM), will appear in the matter of proposed rescheduling of marijuana into Schedule III of the Controlled Substances Act on December 2, 2024.

AAHPM is the professional organization for physicians specializing in Hospice and Palliative medicine. Our membership also includes nurses, social workers, spiritual care providers, pharmacists, and other health professionals committed to improving quality of life for the expanding and diverse population of patients facing serious illness, as well as their families and caregivers.

Dr. Kollas currently serves as the medical director of Palliative and Supportive Care at Orlando Health Cancer Institute. As a hospice and palliative care physician and member of AAHPM, he has been a long-time advocate for maintaining legitimate access to controlled pain medications that can manage pain and other symptoms for certain patients with serious illness. He has also presented a session during an AAHPM conference on Medical Marijuana for Palliative Care Providers and has also written on the topic.

This matter is of particular concern to both Dr. Kollas and AAHPM as it could have an impact on our patient populations and serve to alleviate patient suffering. Cannabis products can provide benefit for some patients with serious illness in treating nausea, cachexia (lack of appetite) and neuropathic pain for whom other treatments may have been ineffective.

The issues we would like to address during the hearing include:

1) the proposed change of marijuana from schedule I to schedule III reflects the currently available evidence demonstrating legitimate medical uses for marijuana when provided under appropriate medical supervision. Allowing the medical use of marijuana can provide even incremental benefits that can be meaningful to patients who are suffering.
2) the proposal would enable more widespread research on both the clinical uses and management of marijuana, which would create more rigorous evidence on appropriate dosing, frequency, and route of administration; support the development of new pharmaceutical products that may aid in palliation of symptoms; and provide additional evidence on the risks of marijuana use.
3) DEA should provide clear guidance to specify which products may or may not be prescribed; offer training and educational resources for the prescriber community; and detail any restrictions or limitations that may apply, including additional requirements that would need to be met to prescribe marijuana products.

AAHPM and Dr. Kollas will state our support for the above items and provide rationale on the need for this proposed rescheduling of marijuana.

All notices to be sent pursuant to this appearance should be addressed to:

Wendy Chill
4 Rickland Road
Parsippany, NJ 07054
wchill@aahpm.org

Respectfully yours,

Wendy-Jo Toyama, MBA FASAE CAE
CEO

AMERICAN PSYCHOLOGICAL ASSOCIATION

September 30, 2024

Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Administrator Milgram:

On behalf of the American Psychological Association (APA), I am writing to request our participation in the December 2, 2024 Drug Enforcement Administration hearing with respect to the proposed rescheduling of marijuana into schedule III of the Controlled Substances Act. (Docket No. DEA-1362).

APA is the largest scientific and professional organization representing psychology in the United States, with a membership of nearly 157,000 clinicians, researchers, educators, consultants, and students. Our members include world-leading experts in the behavioral pharmacology and toxicology of cannabis (aka “marijuana”) and its derivatives (e.g., THC, CBD), drug addiction, abuse liability, regulatory science, and clinicians with expertise in the treatment of health disorders for which cannabis is purported to offer therapeutic benefit (e.g., autism, anxiety, depression, post- traumatic stress disorder, chronic pain).

From an addiction psychology and public health perspective, we are concerned that the proposed rule does not differentiate types of cannabis products. The potential risk of addiction, harm, and/or therapeutic value varies considerably based on the chemical composition, dose, and/or intended route of administration. For example, current science shows no evidence of abuse liability for several phytocannabinoids (e.g., cannabidiol (CBD), cannabigerol (CBG), tetrahydrocannabivarin (THC-V), etc.) as well as any cannabis product that is topically administered, including those containing delta-9-THC. In contrast, delta-8-THC and hexahydrocannabinol (HHC), chemical entities commonly found in unscheduled “hemp” products have the same or greater abuse liability and less evidence of therapeutic potential compared with delta-9-THC. Thus, the term "marijauna" is insufficient for regulation of the diverse array of retail products that currently fall under this category, and not all retail products derived from “marijuana” are appropriate for Schedule III by definition.

In addition, it appears that the proposed rule fails to provide a regulatory path by which cannabis products can be manufactured, distributed, and sold under federal law in the

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Washington, DC 20002-4242
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202.336.6123 TDD

AMERICAN PSYCHOLOGICAL ASSOCIATION

absence of FDA approval and maintains the current problem of incongruence between federal and state law for most of the country.

We recommend a revised rule which divides and schedules cannabis in separate categories based on chemical composition and intended route of administration in a manner that is consistent with the definitions provided in the Controlled Substances Act, the laws regarding access to medical cannabis in most states, and the urgent need to facilitate research into the health effects of cannabis use.

Thank you for the opportunity to request participation in this critical hearing on the rescheduling of “cannabis”. Should you have any questions, please contact Krysta Jones, Director, Congressional and Federal Relations, at knjones@apa.org.

Sincerely,

Katherine B. McGuire
Chief Advocacy Officer

APA.ORG

750 First Street, NE
Washington, DC 20002-4242

202.336.5500
202.336.6123 TDD

Date: September 30, 2024

To: Drug Enforcement Agency Administrator

From: Andrew DeAngelo, Medical Cannabis Subject Matter Expert

Re: Request to testify at the Administrative Rule Change Hearing on 12/2/2024 regarding rescheduling cannabis from Schedule 1 in the CSA to Schedule 3 in the CSA

Dear Administrator,

I am an interested party and medical cannabis expert who has been adversely affected by cannabis being placed in the Controlled Substances Act of 1970. I am going on record opposing the rule change because cannabis should never have been placed in the CSA to begin with. The effort to reschedule cannabis into Schedule 3 is, therefore, a misguided recommendation by the Department of Health and Human Services who did not consider the origin story of the Scheduling of cannabis.

While this argument may not be in direct relation for this rule change, it is my assertion that the administrator must review the circumstances that originally led cannabis to be classified in Schedule 1. Those circumstances reveal a biased approach to drug policy by the Nixon administration. I refer to this argument as the "original sin" argument.

I have submitted my original sin comment regarding this rule (Comment ID: DEA-2024-0059-30476[1]) and it is my request to testify at this hearing outlining the arguments I made in my comment which are as follows:

In 1976, at age 18, my brother Steve was convicted of federal cannabis possession at Dulles Airport and served many months in federal prison for this "crime." I was 9 years old and visiting my brother in prison was one of the most traumatic events of my life. As a child, I knew my brother was a good person who had done no harm to anyone else, and that his work with cannabis in no way harmed our family until this conviction and prison sentence. I did not know much more than that at age 9, but I knew my brother did not belong in prison.

[1] https://www.regulations.gov/comment/DEA-2024-0059-30476

That was just a few years after the CSA was enacted. Since then, members of the Nixon administration[2], including the former president[3] himself, have either gone on record explaining that the inclusion of cannabis in the CSA was motivated by racial and anti-war politics and not by public health or safety, or have lamented people having long prison sentences for cannabis. These were the most conservative and "law and order" elected officials of the era.

These are statements made by the architects of the CSA; even they were not true believers in placing cannabis in the most restrictive category in the CSA. If bias was the motivation to classify cannabis in the CSA and not science, then the Administrator must take these newly revealed historical facts into account. The Administrator may not be thorough in her consideration of this rule change without taking the original sin argument into account during this administrative hearing.

Further evidence of the original sin lies in the Shafer commission report[4]. President Nixon appointed a federal commission to study marijuana in society before and after the enactment of the CSA. This commission was chaired by a conservative former Republican governor from Pennsylvania named Raymond Shafer.

The Shafer Commission conducted thousands of hours of interviews with subject matter experts in drug policy, law enforcement, psychology, social sciences, a variety of medical doctors, and advocates for and against marijuana. The formal recommendation of the Shafer Commission was to decriminalize marijuana and to place no American in prison for its use. The findings of the Shafer Commission—published two years after the CSA was passed and signed into law—were ignored by the Nixon administration, the Congress, and the DEA. This excerpt from Wikipedia sums up the timeline and narrative best:

"While the Controlled Substances Act was being drafted in a House committee in 1970, Assistant Secretary of Health Roger O. Egeberg had recommended that marijuana temporarily be placed in Schedule I, the most restrictive category of drugs, pending the Commission's report. On March 22, 1972, the Commission's chairman, Raymond P. Shafer, presented a report to Congress and the public entitled 'Marihuana, a Signal of Misunderstanding,' which favored ending marijuana prohibition and adopting other methods to discourage use. The report was republished as a Signet Books New American Library paperback in 1972. The Commission's report said that while public sentiment tended to view marijuana users as dangerous, they actually found users to be more timid, drowsy and passive. It concluded that cannabis did not cause widespread danger

[2] Dan Baum, "Legalize It All," Harper's, April 2016, https://harpers.org/archive/2016/04/legalize-it-all/
[3] Tom Angell, "Nixon Admitted Marijuana Is 'Not Particularly Dangerous' In Newly Discovered Recording," Marijuana Moment, September 2024, https://www.marijuanamoment.net/nixon-admitted-marijuana-is-not-particularly-dangerous-in-newly-discovered-recording/
[4] United States Commission on Marihuana and Drug Abuse, "Marihuana: A Signal of Misunderstanding", (New York: New American Library, 1972), https://archive.org/details/marihuanasignalo00unitrich)

to society. It recommended using social measures other than criminalization to discourage use. It compared the situation of cannabis to that of alcohol."

My own family experience with the CSA motivated me to become an advocate while in graduate school and later as co-owner of a medical cannabis dispensary in California from 2006 until 2020. The nonprofit dispensary, Harborside Health Center[5], was one of the first licensed medical cannabis dispensaries in America after the City of Oakland issued the first licenses following the passage of California's Proposition 215 in 1996.

As director of operations for Harborside Health Center, I witnessed the firsthand benefits of medical cannabis to thousands of people suffering from cancer, multiple sclerosis, PTSD, and addiction. Observing these stories inspired me to go on national television and give the first CBD cannabis tincture to a child with epilepsy[6]; the media attention this received inspired parents all over the world to become medical cannabis advocates for their epileptic children.

Six months later, the Department of Justice attempted to shut down Harborside Health Center with a forfeiture action which was subsequently defeated[7] in landlord/tenet court in California. The company's attempts to litigate the IRS regarding tax code 280E[8] were not as successful. As the administrator is aware, IRS tax code 280E is a large burden on the legal cannabis businesses at the state level. Harborside Health Center asserted in court that IRS tax code 280E was harmful to medical cannabis patients and businesses and should not be applied to them. The courts did not agree with these arguments after years of litigation.

My point in describing this narrative is to establish my credentials as a subject matter expert when it comes to medical cannabis, the CSA, and the current classification of marijuana within the CSA. My family has been negatively impacted by the CSA. The nonprofit organization I founded and the patients they served have been negatively impacted by the CSA and IRS tax code 280E. And I have spent my entire adult life studying, advocating, and establishing organizations that work with medical cannabis and the patients this plant works to heal.

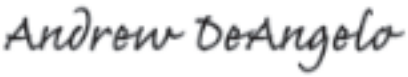
None of this should have occurred at all if the federal government had accepted the findings of the Shafer commission and decriminalized and rescheduled cannabis upon publishing of the

[5] Roger Parloff, "How marijuana became legal," CNN Money, September 18, 2009, https://money.cnn.com/2009/09/11/magazines/fortune/medical_marijuana_legalizing.fortune/
[6] Lee Romney, "On the frontier of medical pot to treat boy's epilepsy," Los Angeles Times, September 13, 2012, https://www.latimes.com/local/la-me-customized-marijuana-20120914-story.html
[7] MJBizDaily Saff, "In major victory, Harborside civil forfeiture case dropped," MJBiz, May 3, 2016, https://mjbizdaily.com/in-major-victory-harborside-civil-forfeiture-case-dismissed/
[8] Eric Sandy, "Tax Court Reinforces IRS Code 280E in Harborside Ruling," Cannabis Business Times, December 3, 2018, https://www.cannabisbusinesstimes.com/legislation-and-regulation/adult-use-legalization-bill/news/15694491/tax-court-reinforces-irs-code-280e-in-harborside-ruling

Docket No. DEA-1362
Request to Testify at Administrative Hearing
Andrew DeAngelo

Shafer commission report. I formally request an opportunity to testify and put forth these and other related arguments during the administrative hearing.

Thank you for your consideration.



ANDREW DEANGELO

September 30, 2024

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ
8701 Morrissette Dr.
Springfield, VA 22152

Subject: Notice of Appearance

Dear Sir:

Please take notice that **Ari Kirshenbaum, PhD** is requesting to appear in the matter of **Docket No. DEA-1362** regarding the DEA's receipt of factual evidence and expert opinion regarding whether marijuana should be transferred to Schedule III of the list of controlled substances.

In the matter of Docket No. DEA-1362, Dr. Kirshenbaum is requesting to testify as an independent researcher with established expertise in the field of marijuana science. Dr. Kirshenbaum has over 20 years of experience in psychopharmacology, and as a principal investigator, has received over $1 million of grant funding from the National Institutes of Health and the National Science Foundation for substance use research. Most germane to cannabis policy is Dr. Kirshenbaum's research related to cannabis-related impairment of the skills needed for motor vehicle operation. Dr. Kirshenbaum is Professor Emeritus of Psychology and has published academic papers on many topics including medical and legal ethics, toxicology, neurobiology, and behavioral economics. Currently, Dr. Kirshenbaum is Senior Scientist at Advocates for Human Potential and in that role also serves as a Scientific Advisor for Cannabis Public Policy Consulting, LLC.

Dr. Kirshenbaum wishes to testify in regard to the public comment he submitted in this matter alongside his colleague Dr. Michael Sofis (Comment ID: DEA-2024-0059-42370, submitted July 22, 2024). Dr. Kirshenbaum and Dr. Sofis conducted a survey of 39 nationally renowned researchers with expertise in marijuana science, garnering their informed opinions on the appropriateness of marijuana being transferred to either Schedule II or Schedule III of the list of controlled substances. The surveyed scientists have received a combined total of $78 million in federal funding for their marijuana research and have a collective 415 years of research knowledge in marijuana science. The results of the scientific consensus survey indicated that marijuana is most accurately characterized as a Schedule III substance, with 86% of expert respondents agreeing that marijuana as a Schedule III substance will not harm public health. Dr. Kirshenbaum intends to testify to the content, methodologies, and results of this survey.

Dr. Kirshenbaum agrees with the consensus of the 39 scientists cited in the aforementioned survey that marijuana is most appropriately placed in Schedule III of the list of controlled substances.

All notices to be sent pursuant to this appearance should be addressed to:
Dr. Ari Kirshenbaum
409 Colby Hill
Lincoln, Vermont, 05443
Respectfully yours,

Certificate of Service

I certify that this document was filed with the Court via the court's electronic filing system, on the 17th day of February, 2025, and an electronic copy was served on all counsel of record via the CM/ECF system on the same date. I further certify that I have mailed the foregoing document via first class mail, postage paid, to those parties or their counsel who are not registered through the CM/ECF system.

/s/Austin T. Brumbaugh
Austin T. Brumbaugh